UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v. Civil No. 08-cv-00358-JL

Mutual Pharmaceutical Company, Inc.

SUMMARY ORDER

Attached are the court's rulings on Mutual's objections to the deposition testimony of one of Bartlett's potential witnesses, Robert Dettery, who has been deemed unavailable to testify at trial under Rule 32(a)(4) of the Federal Rules of Civil Procedure (see doc. 275).

SO ORDERED.

Joseph N. Laplante
United States District Judge

Dated: August 17, 2010

cc: Bryan Ballew, Esq.
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Bartlett v Mutual

Witness_ Robert Dettery - Vol. 1.txt: 1:1 - 1:22

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE
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4
5 KAREN L. BARTLETT and
GREGORY S. BARTLETT,
6 Plaintiffs,
Case No.: 08-cv-358-JL
7 Judge Joseph N. Laplante
V
8
9 MUTUAL PHARMACEUTICAL
COMPANY, INC. and UNITED
10 RESEARCH LABORATORIES, INC,
Defendants.
11
12
13 Videotaped deposition of
14 ROBERT DETTERY, taken at the law offices
15 of Segal, McCambridge, Singer & Mahoney,
16 Ltd., United Plaza, 30 South 17th
17 Street, Suite 1700, Philadelphia,
18 Pennsylvania, on Friday, August 28,
19 2009, at 9:10 a.m., before Jennifer L.
20 Bermudez, a Registered Professional
21 Reporter, and Notary Public, pursuant to
22 notice.

Witness_ Robert Dettery - Vol. 1.txt: 5:18 - 6:9

Q. What do you do for a living,
19 Mr. Dettery?
20 A. I am a vice president of
21 regulatory affairs.
22 Q. For...?
23 A. Mutual Pharmaceutical Company.
24 Q. And you have held that position
25 for how long?
00006
1 A. Since 1993.
2 Q. And what was your position before
3 that?
4 A. I was director of regulatory
5 affairs at Mutual Pharmaceutical
6 Company.
7 Q. And you held that position since
8 when?
9 A. Since 1989.

Witness_ Robert Dettery - Vol. 1.txt: 6:12 - 6:19

Q. You joined Mutual in '89, 20 years
13 ago?
14 A. Yes.
15 Q. And so in that 20 years, you have
16 either been the director of regulatory
17 affairs or now you are the vice
18 president of regulatory affairs?
19 A. Correct.

Witness_ Robert Dettery - Vol. 1.txt: 7:5 - 8:11

Q. And when was Mutual established?
A. Mutual was established in 1984.
Q. And Mutual is owned by who?
A. Presently, it's privately owned by an investment group and by our president/CEO.
Q. And who is that?
A. The president and CEO, his name is Dr. Richard Roberts.
Q. What is the relationship between Mutual Pharmaceutical Company and URL Pharma, Inc., formerly known as Pharmaceutical Holding or URL Pharma?
A. Mutual and URL are separate, but related business entities, under a common ownership and common management. And the common ownership is the -- was previously known as Pharmaceutical Holdings, it's now known as URL Pharma.
Q. What are the other separate business entities owned by URL Pharma,

Objection (7:7 to 7:13):
-402

Ruling: Sustained.

00008
other than Mutual?
A. There's AR Scientific, Incorporated, and AR Holding.
Q. So there are basically three legs, as you understand it, to URL, AR Scientific, AR Holding, and Mutual Pharmaceutical?
A. I would say AR Scientific, Mutual Pharmaceutical, and URL, which has recently now been changed to URL Distributing.

Objection (7:14 to 8:11):
-402
-403 (Mutual is only defendant)

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 9:9 - 9:23

Q. How many ANDAs does Mutual presently have? A best estimate is fine.
A. An estimate, around 250.
Q. And about four NDAs?
A. Yes.
Q. And what are those four NDAs?
A. An NDA for Bactrim tablets and an NDA for Qualaquin capsules. We have an NDA for Colcrys tablets.
Q. Can you spell that, please.
A. C-O-L-C-R-Y-S.
Q. Okay.
A. And we have an NDA for Fibricor tablets.

Objection (9:9 to 11:3):
-402

Ruling: Overruled. Some limited reference to other drugs that Mutual manufactures is permissible as background information.

Witness_ Robert Dettery - Vol. 1.txt: 10:22 - 11:3

Q. And how long has Mutual held the NDA for Bactrim?
A. I believe we purchased it around 2004.

00011

1 Q. When in 2004?
2 A. It was late in the year, November
3 or December, something like that.

Witness_ Robert Dettery - Vol. 1.txt: 11:4 - 11:7

Q. And when did Mutual start its
5 analysis, due diligence investigation of
6 whether or not it might want to purchase
7 Bactrim tablet's NDA?

Objection:
-402

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: Page 11, Line 10

THE WITNESS: I don't know.

Objection:
-402

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 15:3 - 15:6

Q. So since you began at Mutual in
4 1989, Mutual was an ANDA holder for the
5 generic Bactrim, correct?
6 A. Correct.

Objection (15:3 to 15:9):
-402
-403

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: Page 15, Line 9

THE WITNESS: Correct.

Witness_ Robert Dettery - Vol. 1.txt: 15:23 - 17:24

Has Mutual manufactured generic
24 Bactrim and then an RLD Bactrim in only
25 one place since you have been with
00016
1 Mutual or many places?
2 A. One place.
3 Q. Where is that place?
4 A. At our main facility, 1100
5 Orthodox Street, Philadelphia.
6 Q. And what company or companies'
7 names appear on that main facility?
8 A. I don't understand your question.
9 Q. Sure.
10 If we looked on your Web page,
11 would it say URL Pharma on the marquee
12 before you walked into that location?
13 A. I believe it does say URL Pharma.
14 Q. Is there a place where you
15 would -- headquarters where you would
16 see Mutual Pharmaceutical on any marquee
17 or is Mutual contained within URL Pharma
18 at that location at that address?
19 A. Mutual is contained within URL
20 Pharma.
21 Q. And these separate businesses with
22 a common ownership by URL Mutual, AR
23 Scientific, AR Holding, and URL
24 Distributing, is it also true for those
25 three entities that they have no
00017
1 headquarters, but they all do business
2 out of that same address under the
3 marquee URL Pharma?
4 A. That's correct.

5 Q. And approximately how many
6 employees are there now of URL Pharma
7 and its various subsidiaries?
8 A. Approximately 700.
9 Q. And '07 sales were greater than
10 $480 million?
11 A. I'm not sure.
12 Q. And if it says $480 million on the
13 URL Pharma website, is that something
14 that you would dispute or does it sound
15 familiar to you?
16 A. I have no reason to dispute it.
17 If it's truly on the website, then I
18 would have to accept that it would be
19 correct.
20 Q. And if I just used the number,
21 does it sound correct to you that '07
22 sales were greater than $450 million?
23 Does that sound correct or outlandish to
24 you?

Objection (15:23 to 18:3):
-402
-403 (sales not only irrelevant, but also not Mutual's)

Ruling: Sustained as to lines 17:9 through 18:3. Otherwise overruled.

Witness_ Robert Dettery - Vol. 1.txt: 18:2 - 18:3

THE WITNESS: It sounds like
3 it would likely be correct.

Witness_ Robert Dettery - Vol. 1.txt: 19:14 - 20:8

Q. Is it correct to state,
15 Mr. Dettery, that you are the top
16 regulatory affairs person within URL for
17 all its ANDAs and NDAs?
18 A. Within URL Pharma, yes.
19 Q. And if I ask you the same question
20 for Mutual, would the answer be the same
21 for Mutual?
22 A. Yes.
23 Q. Of the 250 approximate ANDAs, I
24 think I asked if they -- how many there
25 were for URL, how many approximate ANDAs
00020
1 are under Mutual's name?
2 A. All of the ANDAs are under
3 Mutual's name.
4 Q. Okay. How many of the four NDAs
5 are under Mutual's name?
6 A. None.
7 Q. What name are they under?
8 A. AR Holdings.

Objection (19:23 to 20:8):
-402
-403

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 21:13 - 21:16

Q. Does Mutual still have a generic
14 allopurinol on the market?
15 A. I think we are selling one
16 strength of it currently.

Objection:
-402

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 24:9 - 24:20

Q. Is tolmetin the only other NSAID
10 that Mutual has ever sold other than
11 sulindac?

12 A. No.
13 Q. What are the other ones?
14 A. Indomethacin. At one time we sold
15 ibuprofen. That's all I remember at the
16 moment.
17 Q. Okay. So the only four you
18 remember are tolmetin, indomethacin, the
19 formerly sold ibuprofen, and sulindac?
20 A. That's all I remember now, yes.

Objection:
-402
-403

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 26:4 - 26:22

Q. Do you understand, Mr. Dettery,
5 that you have been designated by
6 attorneys for Mutual to provide
7 testimony on behalf of the corporation
8 for a number of topics pursuant to a
9 deposition notice?
10 A. Yes.
11 Q. Please tell the ladies and
12 gentlemen of the jury what regulatory
13 affairs is.
14 A. Well, regulatory affairs is the
15 department within the company that deals
16 with the regulatory agencies,
17 particularly FDA and DEA, and we are
18 responsible for the submissions of
19 applications to FDA.
20 In our company, we are also
21 responsible for basically any
22 interaction between FDA and DEA.

Witness_ Robert Dettery - Vol. 1.txt: 27:8 - 27:14

Q. What is the Physicians' Desk
9 Reference?
10 A. It's a book of -- a published
11 document, also now available online, in
12 which brand companies will pay to have
13 their product inserts published so that
14 physicians have a reference source.

Witness_ Robert Dettery - Vol. 1.txt: 29:2 - 29:4

To your knowledge, is there a
3 Bactrim label in the PDR?
4 A. To my knowledge, it's not.

Objection:
-402
-403

Ruling: Overruled. This testimony about Bactrim is later linked up to testimony about how Bactrim's label warned of SJS/TEN (see lines 126:17 through 127:15) and is thus relevant to whether Sulindac's different warning of SJS/TEN avoided an unreasonable risk of harm.

Witness_ Robert Dettery - Vol. 1.txt: 29:13 - 29:20

Is that the 2000 Bactrim label
14 that's published in the PDR?
15 A. Well, it's the Bactrim insert, and
16 the bottom of the page does indicate
17 it's the 2000 PDR, so it appears to be.
18 Q. So this is a place where a doctor
19 can go look for the risk benefit profile
20 of Bactrim, correct?

Objection (29:13 to 30:15):
-402
-403

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 29:23 - 30:12

THE WITNESS: Yes, this would

24 be available to a doctor. He could
25 refer to it.
00030
1 BY MR. JENSEN:
2 Q. What are the purpose of labels
3 like the one we are looking at for
4 Bactrim?
5 A. To instruct the health care
6 professional in the safe and effective
7 way of using the product.
8 Q. And you are a regulatory affairs
9 expert, which means you know a lot about
10 the regulations which govern what needs
11 to be in a label and what shouldn't be
12 in a label, correct?

Witness_ Robert Dettery - Vol. 1.txt: Page 30, Line 15

THE WITNESS: Yes.

Witness_ Robert Dettery - Vol. 1.txt: 31:2 - 31:4

You know that the regulations in
3 part say that a label for a drug cannot
4 be false in any particular, correct?

Objection (31:2 to 31:22):
-402
-702 (not a qualified expert)
-Not a designated expert under 26(a)(2)

Ruling: Sustained. The witness may not testify about the meaning of FDA regulations.

Witness_ Robert Dettery - Vol. 1.txt: 31:7 - 31:19

THE WITNESS: Well, yes. The
8 labeling is part of an application and
9 the application cannot contain false
10 information. So I would say then the
11 answer to your question is that's
12 correct.
13 BY MR. JENSEN:
14 Q. Okay. And let's separate it. If
15 a doctor is seeking out information
16 about a label, he doesn't have access to
17 the drug company's application you are
18 referring to, he or she just has access
19 to the label, correct?

Witness_ Robert Dettery - Vol. 1.txt: Page 31, Line 22

THE WITNESS: Correct.

Witness_ Robert Dettery - Vol. 1.txt: 33:6 - 33:8

Isn't it
7 true the regulations state that labels
8 cannot be misleading in any particular?

Objection (33:6 to 36:12):
-402
-602
-Not a qualified expert
-Not a designated expert under 26(a)(2)
-Calls for opinion testimony from a law witness

Ruling: Sustained as to lines 33:11 through 33:21 and as to lines 35:12 through 36:2. Otherwise overruled.

Witness_ Robert Dettery - Vol. 1.txt: 33:11 - 33:18

THE WITNESS: Yes.
12 BY MR. JENSEN:
13 Q. Isn't it true that the -- you
14 agree that the purpose of the
15 regulations is that labels can neither
16 overstate the benefits associated with a
17 drug nor can they understate the risks
18 associated with a drug?

Witness_ Robert Dettery - Vol. 1.txt: 33:21 - 34:1

THE WITNESS: That's correct.
22 BY MR. JENSEN:
23 Q. Why is it important that labels
24 neither overstate the benefits nor
25 understate the risks associated with a
00034
1 drug?

Witness_ Robert Dettery - Vol. 1.txt: 34:4 - 34:16

THE WITNESS: So the doctor
5 has a clear understanding of the usage
6 of the product.
7 BY MR. JENSEN:
8 Q. Do you agree that when a doctor
9 lacks a clear understanding of the
10 product, if, hypothetically, a label
11 overstated benefits or understated
12 risks, it might, might, lead to the use
13 of the product when that doctor might
14 not have otherwise done it had they
15 known the accurate benefit and risk
16 profile?

Witness_ Robert Dettery - Vol. 1.txt: 34:19 - 35:2

THE WITNESS: That's
20 possible, yes.
21 BY MR. JENSEN:
22 Q. And that's the obvious purpose of
23 making sure the labels doesn't overstate
24 risks -- excuse me -- that's the obvious
25 purpose of having a label that does not
00035
1 overstate benefits nor understate
2 risks. Fair?

Witness_ Robert Dettery - Vol. 1.txt: Page 35, Line 5

THE WITNESS: Yes.

Witness_ Robert Dettery - Vol. 1.txt: 35:12 - 35:15

Q. There's also regulations that very
13 much in detail state what information
14 needs to be in what specific section of
15 a label, correct, Mr. Dettery?

Witness_ Robert Dettery - Vol. 1.txt: 35:18 - 35:24

THE WITNESS: Yes.
19 BY MR. JENSEN:
20 Q. And those sections include the
21 Warnings section, the Indications and
22 Usage section, the Precaution section,
23 and the Adverse Reaction section,
24 correct?

Witness_ Robert Dettery - Vol. 1.txt: 36:2 - 36:6

THE WITNESS: Yes.
3 BY MR. JENSEN:
4 Q. And tell us, Mr. Dettery, what the
5 purpose of the Warnings section of the
6 label is.

Witness_ Robert Dettery - Vol. 1.txt: 36:9 - 36:12

THE WITNESS: To provide the
10 health care professional with the
11 significant warnings pertaining to the
12 use of the product.

Witness_ Robert Dettery - Vol. 1.txt: 37:5 - 37:12

My question is, don't you agree
6 that the regulations require that when a
7 serious adverse reaction is associated
8 with a drug, and serious, as you know,
9 is defined as one that can lead to death
10 or require hospitalization, that such an
11 adverse reaction needs to be put in the
12 Warnings section of the label?

Objection (37:5 to 37:17):
-402
-602
-Not a qualified expert
-Not a designated expert under 26(a)(2)
-Calls for opinion testimony from lay witness

Ruling: Sustained. The witness may not testify about the meaning of FDA regulations.

Witness_ Robert Dettery - Vol. 1.txt: 37:16 - 37:17

THE WITNESS: No, I don't
17 understand the regulations to say that.

Witness_ Robert Dettery - Vol. 1.txt: 38:5 - 38:14

Q. Is it your testimony that you
6 don't know whether or not the
7 regulations say that when a reaction is
8 serious, which they define as one that
9 can lead to death or require
10 hospitalization, that such an adverse
11 reaction needs to be put in the Warnings
12 section, is it your testimony you don't
13 know one way or the other or you are
14 disagreeing with that proposition?

Objection (38:5 to 38:15):
-402
-602
-Not a qualified expert
-Not a designated expert under 26(a)(2)
-Calls for opinion testimony from lay witness
-Calls for speculation

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 38:17 - 38:19

THE WITNESS: I'm saying I
18 can't answer without referring to the
19 regulations.

Witness_ Robert Dettery - Vol. 1.txt: 40:14 - 40:22

Do you agree that the definition
15 of a serious adverse reaction is one
16 that can lead to death or require
17 hospitalization?
18 A. Yes.
19 Q. And that understanding that you
20 have comes from the regulations,
21 correct?
22 A. Yes.

Objection (40:14 to 41:7):
-402
-602
-Not a qualified expert
-Not a designated expert under 26(a)(2)
-Calls for opinion testimony from law witness

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: Page 41, Line 7

A. Yes.

Witness_ Robert Dettery - Vol. 1.txt: 41:19 - 41:24

When an adverse event that's
20 associated with a drug is serious, as we
21 both agree is one that can lead to death
22 or require hospitalization, it has legal
23 ramifications as to where it needs to be
24 put in the label, right?

Objection (41:19 to 42:5):
-402
-602
-Calls for speculation
-Not a qualified expert
-Not a designated expert under 26(a)(2)
-Calls for opinion testimony from lay witness

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 42:3 - 42:5

THE WITNESS: Again, I would
4 need to refer to the regulations in
5 order to answer that.

Witness_ Robert Dettery - Vol. 1.txt: 42:7 - 42:16

Q. How many annual reports have been
8 filed in relation to sulindac since its
9 market approval?
10 A. Well, if it was approved in 1991,
11 there would be approximately 17 annual
12 reports.
13 Q. Are they all still in the custody
14 and possession of Mutual, those 17
15 annual reports?
16 A. Probably not.

Objection:
-402
-403
-602

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 42:25 - 43:3

Where are
00043
1 the annual reports that you are telling
2 me were likely filed with the FDA that
3 have not been produced in this lawsuit?

Objection (42:25 to 44:9):
-402
-403
-602

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 43:7 - 43:12

THE WITNESS: Well, I would
8 assume that they have been destroyed.
9 BY MR. JENSEN:
10 Q. And how many of the 17 annual
11 reports have been destroyed?
12 A. I don't know.

Witness_ Robert Dettery - Vol. 1.txt: 43:17 - 43:19

Q. What's your best estimate of how
18 many of the 17 annual reports for
19 sulindac have been destroyed?

Witness_ Robert Dettery - Vol. 1.txt: 43:22 - 43:24

THE WITNESS: Well, if I had
23 to estimate, I would say maybe about ten
24 or 12.

Witness_ Robert Dettery - Vol. 1.txt: 44:1 - 44:5

Q. And in relation to the 17 that you say were filed, the estimation that ten or 12 have been destroyed would have been in which year, starting from 1991, obviously, through the present?

Witness_ Robert Dettery - Vol. 1.txt: 44:8 - 44:15

THE WITNESS: They would be the oldest ones.
BY MR. JENSEN:
Q. What is your understanding, if you have one, as to when and whether a drug company is ever permitted by regulation or otherwise to destroy annual reports that it's filed?

Objection (44:11 to 44:22):
-402
-403
-602
-Seeks opinion for lay witness not designated under 26(a)(2)

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 44:19 - 44:22

THE WITNESS: Documents may be destroyed a year after the last expiration date of the products produced during that period.

Witness_ Robert Dettery - Vol. 1.txt: 45:9 - 45:15

Q. So it's your testimony that it's your understanding that, for example, if an annual report's filing covering April of 1995 through March of 1996, that in March of 1997 the company would be free to destroy that report for that annual period I just mentioned?

Objection (45:9 to 45:20):
-402
-403
-602
-Seeks opinion for lay witness not designated under 26(a)(2)

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: Page 45, Line 20

THE WITNESS: No.

Witness_ Robert Dettery - Vol. 1.txt: 46:8 - 46:23

Q. What is your understanding in that regard, sir?
A. It is one year after the expiration of the -- the last expiration of the products manufactured during the reporting period.
Q. And what regulation says that?
A. I believe it might be in the GMP regulations.
Q. And GMP stands for what, please?
A. Good manufacturing practices.
Q. So that wouldn't be a regulation, that would be a document produced, as you understand it, by the FDA talking about what you can do or not do in relation to the regulations?

Objection (46:8 to 47:21):
-402
-403
-602
-Seeks opinion for lay witness not designated under 26(a)(2)

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 46:25 - 47:3

THE WITNESS: No.
00047
BY MR. JENSEN:

2 Q. Okay. What is it, then?
3 A. It's a regulation.

Witness_ Robert Dettery - Vol. 1.txt: 47:5 - 47:10

so listen to my example.
6 An annual report that covers March
7 1995 -- excuse me -- April 1995 through
8 March 1996, when, to your understanding,
9 could that annual report for that period
10 be destroyed?

Witness_ Robert Dettery - Vol. 1.txt: 47:12 - 47:21

THE WITNESS: It depends on
13 the expiration of the product. So, say,
14 during that 12-month period, the
15 product -- say, it had a 36-month
16 expiration period. Okay?
17 So if a product was
18 manufactured March 1996, it has a three-
19 year expiration period, it would take it
20 to March 1999, the annual report could
21 be destroyed after March 2000.

Witness_ Robert Dettery - Vol. 1.txt: 54:12 - 54:14

Q. You have seen Regulation 20157
13 before, correct, that I just handed you?
14 A. Yes.

Objection (54:12 to 55:13):
-402
-403
-702
-Calls for opinion from lay witness
-Not designated under 26(a)(2)

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 54:18 - 54:20

Q. And you read that all before you
19 ever heard about this lawsuit, right?
20 That entire regulation, correct?

Witness_ Robert Dettery - Vol. 1.txt: 54:23 - 55:5

THE WITNESS: Most likely,
24 yes.
25 BY MR. JENSEN:
00055
1 Q. And you know that to be the
2 regulation that governs what information
3 needs to be in what section of the
4 package insert that might go into the
5 Physicians' Desk Reference, correct?

Witness_ Robert Dettery - Vol. 1.txt: 55:7 - 55:13

THE WITNESS: Yes.
8 BY MR. JENSEN:
9 Q. And you know that, as we discussed
10 before, the warnings, it's under sub
11 E -- can you read me the first sentence
12 as to what needs to be in the Warnings
13 section of the label?

Witness_ Robert Dettery - Vol. 1.txt: 55:22 - 56:7

A. "Warnings: Under this section

23 heading the labeling shall describe
24 serious adverse reactions and potential
25 safety hazards, limitations in use
00056
1 imposed by them and steps that should be
2 taken if they occur."
3 Q. So now that I have shown you this
4 regulation, do you agree that, based on
5 our conversation, when an adverse
6 reaction is serious, it needs to be in
7 the Warnings section of the label?

Objection (55:22 to 56:10):
-402
-403
-602
-702
-Calls for opinion from lay witness
-Not designated under 26(a)(2)
-Improper publishing

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 56:9 - 56:16

THE WITNESS: That's what it
10 appears to say, yes.
11 BY MR. JENSEN:
12 Q. And you have known for -- is it
13 true that you have known for well over a
14 decade that Stevens-Johnson Syndrome and
15 toxic epidermal necrolysis are serious
16 adverse reactions?

Objection (56:12 to 57:5):
-402
-702
-Calls for opinion from lay witness

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 56:20 - 57:2

THE WITNESS: Are you asking
21 if I personally knew that for over a
22 decade?
23 BY MR. JENSEN:
24 Q. Yes.
25 A. I don't know how long I have known
00057
1 that.
2 Q. You knew it before 2003, correct?

Witness_ Robert Dettery - Vol. 1.txt: Page 57, Line 5

THE WITNESS: Yes.

Witness_ Robert Dettery - Vol. 1.txt: 57:18 - 57:22

Q. Okay. Do you -- are you telling
19 the jury you don't know that SJS and TEN
20 are associated with a high mortality
21 rate, meaning the percent by which they
22 result in death?

Objection (57:18 to 58:12):
-402
-403
-602
-702
-Calls for expert opinion from lay witness
-Not designated under 26(a)(2)

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 57:25 - 58:9

THE WITNESS: I am saying I
00058
1 don't know that it's a serious adverse
2 event because of a -- what you
3 characterize as a high mortality rate.
4 BY MR. JENSEN:
5 Q. Well, you agree that the
6 definition in the CFR is that what is a
7 serious event is an event that can
8 either result in death or require
9 hospitalization, correct?

Witness_ Robert Dettery - Vol. 1.txt: 58:11 - 58:12

THE WITNESS: Among other
12 things, yes.

Witness_ Robert Dettery - Vol. 1.txt: 58:25 - 59:1

Q. You know that SJS and TEN can and
00059
1 do result in death, correct?

Objection (58:25 to 59:15):
-402
-403
-602
-702
-Calls for expert opinion from lay witness
-Not designated under 26(a)(2)

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 59:4 - 59:8

THE WITNESS: Yes.
5 BY MR. JENSEN:
6 Q. Okay. And you know that SJS and
7 TEN can and do require hospitalization,
8 correct?

Witness_ Robert Dettery - Vol. 1.txt: 59:10 - 59:13

THE WITNESS: Yes.
11 BY MR. JENSEN:
12 Q. You know that SJS and TEN can and
13 do result in blindness, correct?

Witness_ Robert Dettery - Vol. 1.txt: Page 59, Line 15

THE WITNESS: No.

Witness_ Robert Dettery - Vol. 1.txt: 60:13 - 60:20

Q. Do you have knowledge that Karen
14 Bartlett has undergone a number of eye
15 surgeries?
16 A. No.
17 Q. Do you have knowledge that Karen's
18 eye surgeons and ophthalmologists have
19 frequently described her as legally
20 blind?

Objection (60:13 to 61:15):
-402
-403
-602
-Argumentative

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 60:22 - 61:5

THE WITNESS: No.
23 BY MR. JENSEN:
24 Q. So if I were to represent to you
25 that it's true, because it is, that
00061
1 Karen Bartlett's had now over nine
2 surgeries and she's still legally blind
3 in both eyes, worse than 2200 visual
4 acuity in both eyes, that's completely
5 new information to you?

Witness_ Robert Dettery - Vol. 1.txt: 61:8 - 61:15

THE WITNESS: Yes.
9 BY MR. JENSEN:
10 Q. And if I were to represent to you
11 that everyone, "everyone" defining that
12 as her doctors who treat her, believed
13 her blindness resulted from her SJS and
14 TEN, would that be completely new

15 information to you?

Witness_ Robert Dettery - Vol. 1.txt: 61:18 - 61:25

THE WITNESS: Yes.
19 BY MR. JENSEN:
20 Q. Has it always been true that
21 there's never been a doubt in your mind,
22 since you learned about SJS and TEN,
23 that they constituted serious adverse
24 reactions as defined by the regulations
25 that you understand?

Objection (61:20 to 62:8):
-402
-403
-602
-702
-Calls for expert opinion from lay witness

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 62:4 - 62:8

THE WITNESS: Yes.
5 BY MR. JENSEN:
6 Q. Yes, there's never been any doubt
7 in your mind, correct?
8 A. Correct.

Witness_ Robert Dettery - Vol. 1.txt: 62:18 - 62:21

Q. Nonetheless, SJS and TEN were
19 never in the Warnings section of the
20 sulindac label all the way through the
21 end of 2004, correct?

Objection (62:18 to 62:24):
-Argumentative
-Misleading
-403 (condition in Warning, but not terms SJS and TEN)

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 62:24 - 63:7

THE WITNESS: Correct.
25 BY MR. JENSEN:
00063
1 Q. In 2005, after Karen Bartlett
2 spent over a hundred days in five
3 hospitals and was still on a G-tube,
4 then, for the first time, there was a
5 change to the label and sulindac got an
6 SJS/TEN warning in the Warnings section
7 of the label, correct?

Objection (63:1 to 63:23):
-402
-403
-Foundation
-Misleading (condition is in Warning, but not term)
-407 (Rx date 12/04)

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 63:10 - 63:19

THE WITNESS: I would need to
11 review the labeling history to confirm
12 that.
13 BY MR. JENSEN:
14 Q. You do know that in 2005, the year
15 after Karen Bartlett took sulindac, that
16 there was, for the first time, a label
17 change, which included SJS and TEN in
18 the Warnings section of the label,
19 correct?

Witness_ Robert Dettery - Vol. 1.txt: 63:22 - 63:23

THE WITNESS: That sounds
23 correct, yes.

Witness_ Robert Dettery - Vol. 1.txt: 64:13 - 64:19

In the March 2006 letter before

you is Mutual telling the FDA that it is now changing its label, for the first time since you have been with the company, to have for the first time an SJS and TEN warning in the Warnings section of the label, correct.

Objection (64:13 to 64:22):
-402
-403
-407
-Misleading

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: Page 64, Line 22

THE WITNESS: Correct.

Witness_ Robert Dettery - Vol. 1.txt: 66:18 - 66:22

The March 2006 letter that Mutual provided the FDA is the first time that Mutual would ever have a medication guide that would accompany their label for sulindac, correct?

Objection (66:18 to 67:17):
-402
-403
-407

Ruling: Overruled. The patient medication guide is relevant to the presence and efficacy of a warning to avoid an unreasonable risk of danger. Mutual may request a limiting instruction, if appropriate, to avoid any risk of unfair prejudice.

Witness_ Robert Dettery - Vol. 1.txt: 66:25 - 67:17

THE WITNESS: Yes.
00067
BY MR. JENSEN:
Q. Tell the jury what a medication guide is, please.
A. A medication guide is a document that goes with the product. It's written in layperson's terms and is summarizing the product to the -- how to take the product, the side effects and precautions to take while taking the product, and is intended to be distributed by the pharmacist to each person getting a prescription for that product.
Q. So the medication guide is a document designed for the patient, not the doctor?
A. Correct.

Witness_ Robert Dettery - Vol. 1.txt: 68:12 - 68:17

Q. And for the first time, in March of 2006, two years after Karen Bartlett ingested sulindac, is the first time that a patient-designed medication guide ever accompanied Mutual's sulindac, correct?

Objection (68:12 to 70:23):
-402
-403
-407

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 68:20 - 69:4

THE WITNESS: Correct.
BY MR. JENSEN:
Q. And that March 2006 medication guide, for the first time, advised patients that they should stop their NSAID and call their health care
00069
provider right away if they have any of the following symptoms, and it lists, under those symptoms, skin rash or

4 blisters with fever, correct?

Witness_ Robert Dettery - Vol. 1.txt: Page 69, Line 25

THE WITNESS: Yes.

Witness_ Robert Dettery - Vol. 1.txt: 70:2 - 70:9

Q. And do you understand that was to
3 alert patients that if they got skin
4 rash or blisters with fever, which,
5 unfortunately, are commonly associated
6 when they progress or get worse with SJS
7 or TEN, that if they start to get a skin
8 rash, they should call their doctor
9 right away?

Witness_ Robert Dettery - Vol. 1.txt: 70:12 - 70:20

THE WITNESS: Yes.
13 BY MR. JENSEN:
14 Q. And you agree that, for the first
15 time, in March 2006, two years after
16 Karen Bartlett took sulindac, the label,
17 also for the first time, not only had a
18 warning about SJS and TEN, it actually
19 said that NSAIDs, including sulindac,
20 therefore, caused SJS and TEN, correct?

Witness_ Robert Dettery - Vol. 1.txt: Page 70, Line 23

THE WITNESS: Yes.

Witness_ Robert Dettery - Vol. 1.txt: 74:1 - 75:8

Q. And what you are looking at is a
2 side-by-side comparison of the March '06
3 label and the RLD's label, correct?
4 A. That's correct.
5 Q. Other than the difference between
6 the words Clinoril, the brand name, and
7 sulindac, the generic name, and other
8 minor differences, do you agree,
9 Mr. Dettery, that the sulindac label was
10 always substantively the same as the
11 Clinoril branded label?
12 A. That's correct.
13 Q. I refer your attention to Exhibit
14 3, which is on here. Okay. Does that
15 appear to you to be the Clinoril branded
16 label?
17 This one is dated 2004. You can
18 see it in the bottom of the second
19 page. As published in the Physicians'
20 Desk Reference.
21 A. Yes.
22 Q. And, to your knowledge -- I'm not
23 asking you to tell me what other people
24 think or know, sir, but, to your
25 knowledge, do physicians, as you being a
00075
1 20-year regulatory person, know that if

Objection (74:1 to 75:23):
-402
-403
-407 (Rx date 12/04)

Ruling: Overruled.

2 they are looking for the risk/benefit
3 profile of a drug, they can either look
4 at the RLD drug or they can look at the
5 generic drug, because they know, but for
6 minor differences in words, like brand
7 name versus generic name, they are going
8 to be substantively the same?

Witness_ Robert Dettery - Vol. 1.txt: 75:11 - 75:23

THE WITNESS: Yes.
12 BY MR. JENSEN:
13 Q. So do you agree that if we look at
14 the 2004 brand name label for sulindac,
15 we will substantively know what was in
16 the same time in 2004 for the Mutual
17 sulindac label?
18 A. Yes, I would agree with that.
19 Q. So now let's do that.
20 And do you agree that this 2004
21 brand name label for sulindac doesn't
22 have anything in the Warnings section
23 about SJS or TEN?

Witness_ Robert Dettery - Vol. 1.txt: 76:6 - 76:11

Now that you have reviewed the
7 2004 brand name label for sulindac,
8 isn't it true that the Warnings section
9 says nothing about Stevens-Johnson
10 Syndrome, toxic epidermal necrolysis, or
11 any abbreviation of them?

Objection (76:6 to 78:10):
-402
-403
-602
-702
-Calls for medical opinion from lay witness
-Not designated under 26(a)(2)
-Misleading
-Argumentative

Ruling: Sustained as to lines 77:4 through 77:18. Otherwise overruled.

Witness_ Robert Dettery - Vol. 1.txt: 76:14 - 76:22

THE WITNESS: It does refer
15 to rash, but it does not, that I can
16 see, refer to Stevens-Johnson Syndrome
17 or TEN.
18 BY MR. JENSEN:
19 Q. You would agree, sir, that there
20 is a world of difference between a rash
21 and toxic epidermal necrolysis, do you
22 not?

Witness_ Robert Dettery - Vol. 1.txt: 76:25 - 77:14

THE WITNESS: I'm not a
00077
1 medical professional, so I don't know
2 what a world of difference would be.
3 BY MR. JENSEN:
4 Q. Well, let me define a world of
5 difference for you.
6 Do you agree that a rash, which
7 might be as minor as something that
8 might last three or four days, on your
9 arm or your leg or your scalp, is not
10 anywhere near, in your mind, in your
11 estimation, as serious as toxic
12 epidermal necrolysis, which can result
13 and often does result in half, three-

14 quarters, or all your skin burning off?

Witness_ Robert Dettery - Vol. 1.txt: Page 77, Line 18

THE WITNESS: Well, if you

Witness_ Robert Dettery - Vol. 1.txt: 77:22 - 78:2

Q. You agree, sir, do you not, that
23 telling people of a rash does not put
24 them on notice of a serious adverse
25 reaction that's supposed to be in the
00078
1 Warnings section, like Stevens-Johnson
2 Syndrome or TEN, correct?

Witness_ Robert Dettery - Vol. 1.txt: 78:7 - 78:22

THE WITNESS: All I'm saying
8 is, it does not mention Stevens-Johnson
9 Syndrome in the Warnings section of the
10 previous labeling.
11 BY MR. JENSEN:
12 Q. Now, given that the March 2006
13 label, for the first time, had a
14 medication guide that told patients that
15 if they got a skin rash, which might,
16 heaven forbid, develop into all their
17 skin burning off, that they should call
18 their doctor, and the 2004 label in
19 existence when Karen Bartlett took the
20 drug had no such medication guide, do
21 you agree, sir, that the March 2006
22 sulindac label was better?

Objection (78:12 to 79:5):
-402
-403
-407
-602
-Calls for expert opinion from lay witness
-Not designated under 26(a)(2)
-Argumentative

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 79:2 - 79:5

THE WITNESS: You are asking
3 me for an opinion, and I can't say
4 whether it's better or not. It's
5 different.

Witness_ Robert Dettery - Vol. 1.txt: 79:23 - 80:18

Q. Did you speak with your attorney
24 during the break?
25 A. Yes.
00080
1 Q. Are you ready to continue now?
2 A. Yes.
3 Q. Before our break and before you
4 spoke with the attorney, I asked you
5 about the label in March 2006, which
6 first had a medication guide, which
7 first advised patients to call their
8 doctor if they got a rash or a fever.
9 And I asked you if that label was
10 better than the one that existed when
11 Karen Bartlett took the drug in 2004,
12 which had no medication guide at all for
13 a patient, and you said they are
14 different, but not better.

Objection (79:23 to 80:2):
-402
-403

Ruling: Sustained.

Objection (80:3 to 82:14):
-402
-403
-407
-Calls for expert opinion from lay witness

Ruling: Overruled.

15 My question, sir, is, just
16 defining better as everyone does, wasn't
17 the March 2006 label better than the
18 2004 label?

Witness_ Robert Dettery - Vol. 1.txt: 80:21 - 81:18

THE WITNESS: Well, again, I
22 don't know what you -- what the meaning
23 is as far as you are concerned of what
24 the word "better" is.
25 It is different. Labels
00081
1 change over time and this one is
2 different. Information in them
3 changes. I don't know if you can say
4 one is better than the other.
5 BY MR. JENSEN:
6 Q. Well, if we define better as
7 putting a patient on notice through a
8 medication guide that if they get a
9 rash, they should call their doctor, and
10 their doctor hopefully will tell them to
11 stop taking the drug before it
12 progresses to all their skin burning
13 off, and the prior one had no such
14 mechanism, nothing for the patient to
15 read in that regard, if we limit our
16 definition of better to that, don't you
17 agree that the March 2006 label was
18 better than the 2004 label?

Witness_ Robert Dettery - Vol. 1.txt: 81:23 - 82:9

THE WITNESS: Well, if you
24 are defining better as whether it has a
25 med guide or not, then this one does
00082
1 have a med guide.
2 BY MR. JENSEN:
3 Q. Specifically, this one had a
4 medication guide, the March '06 one,
5 that Karen Bartlett didn't have the
6 benefit of, that first advised patients
7 specifically that if they got a rash or
8 fever, they should call their doctor,
9 correct?

Witness_ Robert Dettery - Vol. 1.txt: 82:12 - 82:14

THE WITNESS: If her incident
13 was before -- before this insert went
14 into effect, then that's correct.

Witness_ Robert Dettery - Vol. 1.txt: 83:13 - 83:15

Do you know that rash and fever
14 are commonly associated with progressing
15 to SJS and TEN?

Witness_ Robert Dettery - Vol. 1.txt: 83:19 - 83:23

Objection (83:13 to 83:23):
-402
-403
-602
-702
-Calls for expert opinion from lay witness
-Plaintiff does not designate answer

Ruling: Sustained.

THE WITNESS: No.
20 BY MR. JENSEN:
21 Q. Do you know that when people get
22 SJS and TEN, they invariably started out
23 with a rash and fever?

Witness_ Robert Dettery - Vol. 1.txt: 88:11 - 88:13

Q. Do you agree that the 2004 label
12 that Ms. Bartlett and her physician had
13 to rely on says nothing of blindness?

Objection (88:11 to 90:7):
-602
-702
-Question requires witness to have medical expertise

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 88:16 - 88:22

THE WITNESS: I do not see
17 the word "blindness" in there.
18 BY MR. JENSEN:
19 Q. Do you agree that the 2004
20 sulindac label that Ms. Bartlett and her
21 physician had to rely on says nothing of
22 a coma?

Witness_ Robert Dettery - Vol. 1.txt: 88:25 - 89:9

THE WITNESS: Again, in my
00089
1 cursory read here, I didn't see the word
2 "coma."
3 BY MR. JENSEN:
4 Q. Do you also agree that the 2004
5 label said nothing of the potential need
6 for a hospital-induced coma, a medical
7 protective coma, or that you might need
8 to be sedated for weeks or months on end
9 after you take sulindac?

Witness_ Robert Dettery - Vol. 1.txt: 89:12 - 89:20

THE WITNESS: I did not see
13 that in that insert.
14 BY MR. JENSEN:
15 Q. Is there anything in the 2004
16 label that says that if you get SJS or
17 TEN, that as much as half or three-
18 quarters, or maybe even all, your skin
19 might exfoliate, slough off, peel off,
20 or, in colloquial terms, burn off?

Witness_ Robert Dettery - Vol. 1.txt: 90:4 - 90:7

A. I did not see that.
5 Q. Are blindness and comas serious
6 adverse reactions, Mr. Dettery?
7 A. Yes.

Witness_ Robert Dettery - Vol. 1.txt: 91:18 - 91:21

Isn't it true that neither
19 blindness nor coma nor SJS nor TEN are
20 anywhere in the Warnings section of the
21 2004 label?

Objection (91:18 to 91:25):
-602
-702
-Question requires witness to have medical expertise

Ruling: Overruled.

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Witness_ Robert Dettery - Vol. 1.txt: 91:24 - 91:25

THE WITNESS: I do not see
it.

Witness_ Robert Dettery - Vol. 1.txt: 92:2 - 92:12

Q. Since Mutual Pharmaceutical
Company learned that Karen Bartlett was
in a coma for weeks or months on end,
and since Mutual Pharmaceutical Company
learned that Karen Bartlett has been,
for the most part, legally blind in both
eyes after three, six, nine, and ten eye
surgeries, most of which have been at
Harvard, what has Mutual Pharmaceutical
Company done to put coma or blindness in
the label?

Objection (92:2 to 93:22):
-402
-403
-407
-Argumentative

Ruling: Sustained (Rule 403).

Witness_ Robert Dettery - Vol. 1.txt: 93:18 - 93:22

THE WITNESS: If I recall the
dates correctly, I believe we learned of
this incident in early 2008, and as far
as I'm aware, we have not had any
labeling changes required since then.

Witness_ Robert Dettery - Vol. 1.txt: 94:24 - 95:6

Isn't it true that since Mutual
Pharmaceutical Company has learned of
00095
Karen Bartlett's blindness, isn't it
true that since Mutual learned of
Karen's coma that she was in for weeks
or months on end, it has done nothing
since it learned to try to put either
coma or blindness in the label?

Objection (94:24 to 95:13):
-402
-403
-407
-Argumentative

Ruling: Sustained (Rule 403).

Witness_ Robert Dettery - Vol. 1.txt: 95:9 - 95:13

THE WITNESS: Well, as I
answered before, there has been no
labeling changes, so you can interpret
that as there being no changes to the
label.

Witness_ Robert Dettery - Vol. 1.txt: 95:25 - 96:16

Q. Isn't it true that Mutual has
00096
never picked up the phone through today,
to your knowledge, and called anyone at
the FDA and said, we, at Mutual, believe
that because blindness and coma are
serious adverse events, and Ms. Bartlett
clearly has had blindness, likely in
both eyes for most of the last four or
five years, she was in a coma for weeks
or months on end, and that's a serious
adverse reaction, we think, you guys,
the FDA, should allow us to, or we think

Objection (95:25 to 96:23):
-402
-403
-407
-Argumentative

Ruling: Sustained.

you guys, the FDA, should require that everyone who sells sulindac should put coma and blindness in the label?
No such hypothetical call has ever occurred, to your knowledge, correct?

Witness_ Robert Dettery - Vol. 1.txt: 96:22 - 96:23

THE WITNESS: To my knowledge, no such call has made.

Witness_ Robert Dettery - Vol. 1.txt: 97:9 - 97:14

Mutual, since it learned of Karen's coma, Mutual, since it learned of Karen's blindness, has never filed a citizen's petition to advocate for a label change to put coma or blindness on the sulindac label, correct?

Objection (97:9 to 98:1):
-402
-403
-407
-Argumentative

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 97:16 - 97:24

THE WITNESS: Correct.
BY MR. JENSEN:
Q. Mutual, since it learned of Karen's blindness and coma, has never sent out a "Dear Doctor" letter to advise doctors that their patients might need a medically-induced coma and might go blind if they take sulindac, have they?

Witness_ Robert Dettery - Vol. 1.txt: Page 98, Line 1

THE WITNESS: No.

Witness_ Robert Dettery - Vol. 1.txt: 98:15 - 98:18

Mutual has never sent out a "Dear Doctor" letter regarding sulindac since 1991 when they started selling it through today in August 2009, correct?

Objection (98:15 to 99:6):
-402
-403
-407
-Argumentative

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 98:22 - 99:3

Q. Mutual has never filed a citizen's petition advocating enhanced or stronger warnings about incidents information regarding SJS and TEN, regarding any
00099
complications of SJS and TEN, like blindness or coma, from 1991 through today, in August 2009, correct?

Witness_ Robert Dettery - Vol. 1.txt: 99:6 - 99:12

THE WITNESS: Correct.
BY MR. JENSEN:
Q. Mutual has always had the ability to file a citizen's petition to advocate for enhanced SJS/TEN warnings or for warnings like blindness and coma for the

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12 sulindac label, correct?

Witness_ Robert Dettery - Vol. 1.txt: 99:15 - 99:20

Objection (99:8 to 99:24):
-402
-403
-702
-Calls for expert opinion from lay witness

Ruling: Sustained.

THE WITNESS: Anyone has that
16 ability to file a citizen's petition.
17 BY MR. JENSEN:
18 Q. And anyone includes you and it
19 includes everyone with whom you work at
20 Mutual, correct?

Witness_ Robert Dettery - Vol. 1.txt: 99:23 - 99:24

THE WITNESS: Yes, it
24 includes Mutual.

Witness_ Robert Dettery - Vol. 1.txt: 101:18 - 101:21

Objection (101:18 to 103:22):
-Argumentative
-402
-403
-Calls for expert opinion from lay witness

Ruling: Sustained.

You understand, Mr. Dettery, that
19 drug companies retain and maintain
20 ultimate responsibility for the content
21 of their label, correct?

Witness_ Robert Dettery - Vol. 1.txt: 101:23 - 102:5

THE WITNESS: No.
24 BY MR. JENSEN:
25 Q. Okay. So it's your understanding
00102
1 that the FDA has ultimate responsibility
2 for the content and accuracy of a label,
3 not the drug companies who sell the
4 drug? Is that your understanding and
5 claim?

Witness_ Robert Dettery - Vol. 1.txt: 102:7 - 102:16

THE WITNESS: My
8 understanding is that the brand company,
9 along with FDA, determines what is to be
10 included in the labeling.
11 BY MR. JENSEN:
12 Q. Do you understand that in this
13 case the presiding judge has ruled
14 against Mutual's claim that they cannot
15 change the label to strengthen or add
16 warnings?

Witness_ Robert Dettery - Vol. 1.txt: 103:7 - 103:14

THE WITNESS: Yes, I was
8 informed of that.
9 BY MR. JENSEN:
10 Q. Do you understand that it was the
11 fourth time this year that a federal
12 judge has ruled that ANDA holders have
13 the unilateral ability to change their
14 labels to add or strengthen warnings?

Witness_ Robert Dettery - Vol. 1.txt: 103:20 - 103:22

THE WITNESS: I was aware

21 there have been one or two previous
22 cases.

Witness_ Robert Dettery - Vol. 1.txt: 109:18 - 109:24

Q. Excluding post-marketing
19 surveillance, excluding keeping your
20 label the same, isn't it true that
21 Mutual never took any affirmative
22 action, from 1991 to 2004, to advocate
23 any enhanced or strengthened warning to
24 the sulindac label?

Objection (109:18 to 110:13):
-Vague
-Ambiguous
-Misstates evidence

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 110:2 - 110:7

THE WITNESS: Strengthened
3 warning regarding SJS?
4 BY MR. JENSEN:
5 Q. Or any adverse reaction, including
6 SJS, TEN, blindness, or coma.
7 A. No.

Witness_ Robert Dettery - Vol. 1.txt: 110:12 - 110:13

Q. No, you never did so, correct?
13 A. Correct.

Witness_ Robert Dettery - Vol. 1.txt: 110:17 - 110:20

Q. You see the fax from the FDA,
18 dated September 2000, advising
19 sulindac -- Mutual of its need to change
20 the sulindac label?

Objection (110:17 to 112:12):
-Vague
-Ambiguous
-Misleading
-402
-403 (unrelated to whether 2004 warning was adequate)

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 110:22 - 111:3

THE WITNESS: Yes.
23 BY MR. JENSEN:
24 Q. And they are telling Mutual, the
25 FDA, that they need to change the label
00111
1 that was changed more than five years
2 before that to so-called match or be the
3 same as the branded label, correct?

Witness_ Robert Dettery - Vol. 1.txt: 111:12 - 111:25

THE WITNESS: It says that
13 the most recently approved labeling for
14 Clinoril tablets is attached, the
15 reference listed drug for sulindac, it
16 was approved July 10th, 1995. And then
17 this fax was dated in 2000.
18 BY MR. JENSEN:
19 Q. So we know from this, that more
20 than five years have gone by since the
21 branded label was updated, and Mutual,
22 according to the FDA, still has not
23 updated its label to match the branded
24 label, correct?
25 A. Yes.

Witness_ Robert Dettery - Vol. 1.txt: 112:3 - 112:10

**Q. And we know from 318 that, seven
4 months later Mutual finally did what the
5 FDA requested it to do more than five
6 years after the Clinoril label was
7 changed, and Mutual then in April 2001
8 submitted a label to have it match or be
9 consistent with the brand name label,
10 correct?**

Witness_ Robert Dettery - Vol. 1.txt: 112:12 - 112:18

**THE WITNESS: Yes.
13 BY MR. JENSEN:
14 Q. So why did it take Mutual nearly
15 six years, from July '95 to April 2001,
16 that's three months short of six years,
17 to get the label the same if it's so
18 important that the labels be the same?**

Objection (112:14 to 112:23):
-Vague
-Ambiguous
-Misleading
-402
-403 (unrelated to whether 2004 warning was adequate)

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 112:20 - 113:5

**THE WITNESS: Because we
21 changed our inserts when FDA tells us to
22 change the inserts, and they notified us
23 in 2000 to do so for sulindac.
24 BY MR. JENSEN:
25 Q. Okay. So, let's go with that for
00113
1 a second.
2 Why did it take Mutual seven
3 months, from September 2000 to April
4 2001, if it's so important that labels
5 be the same, to do it?**

Objection (112:25 to 114:10):
-402
-403
-No impact on 2004 warning
-No basis for assumption in question that 7 months is untimely
-Consistent with FDA standards

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 113:7 - 113:21

**THE WITNESS: Well, I don't
8 know why it took seven months to change
9 in this particular case.
10 BY MR. JENSEN:
11 Q. And now let's go back to the first
12 five years.
13 What was Mutual doing in these
14 five years, if it's so important for
15 labels to be the same, and their labels
16 were different in '95 and '96 and '97
17 and '98 and '99, and then in 2000 the
18 FDA has got to tell you your labels are
19 not the same?
20 What happened in those five
21 years?**

Witness_ Robert Dettery - Vol. 1.txt: 113:25 - 114:10

**THE WITNESS: Well, you are
00114
1 making -- you are assuming every label
2 change is a label change that
3 requires -- or is one that is conveying
4 new significant information.**

5 The labeling changes
6 frequently for reference listed drugs,
7 and I can only assume that it took the
8 FDA five years to notify us because it
9 was not -- there were not significant
10 changes in this insert.

Witness_ Robert Dettery - Vol. 1.txt: 126:7 - 126:10

I already marked the PDR
8 label for Bactrim.
9 Can you reference that again,
10 please, sir, if you have it handy there.

Objection (126:7 to 127:15):
-402
-403

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 126:17 - 126:20

And Page 2, just to refresh your
18 recollection, does, in fact, have a
19 bolded, capitalized warning in the
20 Bactrim label for SJS and TEN, correct?

Witness_ Robert Dettery - Vol. 1.txt: 126:23 - 127:4

THE WITNESS: Yes.
24 BY MR. JENSEN:
25 Q. And it also has a bolded,
00127
1 capitalized warning that says, Bactrim
2 should be discontinued at the first
3 appearance of skin rash or any sign of
4 adverse reaction?

Witness_ Robert Dettery - Vol. 1.txt: 127:6 - 127:12

THE WITNESS: Yes.
7 BY MR. JENSEN:
8 Q. All the way up through 2004, there
9 is nothing ever bolded and capitalized
10 in the warning or contraindication that
11 said either of those two things in the
12 sulindac label, correct?

Witness_ Robert Dettery - Vol. 1.txt: 127:14 - 127:21

THE WITNESS: Well, I think
15 we already established that, yes.
16 BY MR. JENSEN:
17 Q. Exhibit 301, sir, in the stack,
18 that's the August 1987 letter from the
19 FDA stating -- advising of receipt of
20 the sulindac application from Mutual,
21 correct?

Witness_ Robert Dettery - Vol. 1.txt: 127:24 - 128:4

THE WITNESS: Well, it
25 acknowledges the receipt.
00128
1 BY MR. JENSEN:
2 Q. And sulindac's application was
3 filed in 1987 and approved in 1981, why
4 did it take about four years?

Objection (128:2 to 128:9):
-402
-403
-Implication of problem that did not exist

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 128:7 - 128:9

THE WITNESS: Why did it take
8 four years to get approval? You have to
9 ask FDA. I don't know.

Witness_ Robert Dettery - Vol. 1.txt: 129:25 - 130:16

Q. Is that is an FDA label
00130
1 acknowledging approval of a waiver that
2 was sought by Mutual for certain
3 reporting, correct?
4 A. That's correct.
5 Q. And the waiver that was sought was
6 what?
7 A. To report the adverse events in
8 the periodic reports in just a summary
9 form, rather than submitting the Med --
10 what's called a MedWatch form for the
11 adverse events.
12 Q. Is that the first waiver of
13 reporting requirements of the Food and
14 Drug Administration that Mutual ever
15 sought in relation to sulindac?
16 A. Yes.

Objection:
-402
-403 (permitted FDA waiver under regulations for trivial adverse events)

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 130:24 - 131:3

Before this waiver was sought,
25 FDA, without any exceptions granted by a
00131
1 waiver, had to comply with all the FDA
2 reporting requirements?
3 A. Yes.

Objection:
-402
-403 (permitted FDA waiver under regulations for trivial adverse events)

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 131:17 - 131:21

And Mutual's reporting
18 requirements included providing medical
19 literature of certain types to the FDA,
20 correct?
21 A. No.

Witness_ Robert Dettery - Vol. 1.txt: 131:24 - 132:8

Q. So it's your belief that Mutual
25 never had to give any medical literature
00132
1 of any type to the FDA for sulindac?
2 A. No. Generic companies do not have
3 to do that.
4 Q. Is there any regulation that says
5 generic companies don't have to do that?
6 A. I don't see any regulation that
7 says generic companies do have to do
8 that.

Witness_ Robert Dettery - Vol. 1.txt: 132:12 - 132:15

Q. Is there any regulation that says

13 generic companies do not have to provide
14 certain types of medical literature or
15 any medical literature to the FDA?

Witness_ Robert Dettery - Vol. 1.txt: 132:20 - 132:21

but I don't recall any
21 regulation to that effect.

Witness_ Robert Dettery - Vol. 1.txt: 133:17 - 133:20

Q. How many NSAIDs have been pulled
18 off the market, in whole or in part, due
19 to the risks of Stevens-Johnson Syndrome
20 or TEN?

Objection (133:17 to 134:24, See next page for 134:16 to 134:24):
-402
-403 (not only other drugs but also drug withdrawals that post-date 12/04)

Ruling: Sustained as to lines 135:18 through 136:11 and as to lines 134:23 through 135:15 (taking the passages in the order they are presented). Otherwise overruled.

Witness_ Robert Dettery - Vol. 1.txt: 133:23 - 134:3

THE WITNESS: I don't know.
24 BY MR. JENSEN:
25 Q. Well, you know Bextra was an NSAID
00134
1 and you know it was withdrawn from the
2 market, in whole or in part, due to SJS
3 or TEN, correct?

Witness_ Robert Dettery - Vol. 1.txt: 134:7 - 134:15

THE WITNESS: No.
8 BY MR. JENSEN:
9 Q. You don't know any of that?
10 A. I didn't know that Bextra was an
11 NSAID.
12 Q. Did you know that Bextra, the
13 drug, was pulled from the market due, in
14 part or in whole, to SJS or TEN?
15 A. No.

Witness_ Robert Dettery - Vol. 1.txt: 135:18 - 136:1

THE WITNESS: Yes.
19 BY MR. JENSEN:
20 Q. And 314.81 is another regulation
21 that you have read before you learned of
22 this lawsuit, correct, sir?
23 A. Yes.
24 Q. And you read it in conjunction
25 with needing to comply with it for ANDA
00136
1 and NDA drugs, correct?

Witness_ Robert Dettery - Vol. 1.txt: 136:3 - 136:15

THE WITNESS: That's correct.
4 BY MR. JENSEN:
5 Q. And under 6(a) there, on Page 3,
6 that defines what clinical data needs to
7 be reported to the FDA, correct?
8 A. I have to find my way here.
9 Oh, you are talking about little
10 Roman numeral vi?
11 Q. Yes, sir.

Bartlett v Mutual

Witness_ Robert Dettery - Vol. 1.txt: 134:16 - 135:15

Q. Did you know that isoxicam was
17 withdrawn from the market due, in whole
18 or in part, because of its risks of SJS
19 and TEN?
20 A. Did I know that?
21 Q. Yes.
22 A. No, I did not.
23 Q. You have seen 314.80, have you
24 not, sir?
25 A. Yes.
00135
1 MR. JENSEN: I don't have a
2 copy. Yes, I do.
3 BY MR. JENSEN:
4 Q. And you have read this regulation
5 a number of times before you learned
6 about this lawsuit, right?
7 A. I have read it a few times.
8 Q. And it pertains to the reporting
9 requirements, in part, for drug
10 companies, correct?
11 A. Yes.
12 Q. And, in part, it tells us that
13 when an event is both serious and
14 unlabeled, it has got to be reported on
15 a 15-day basis, correct?

Objection (134:23 to 140:20, See Page 28 for 135:18 to 136:11 and Page 29 for 136:12 to 140:21):
-Calls for legal opinion; only Court can interpret statutes on regulations

Ruling: Sustained.

---

12 A. Okay.
13 Q. And 6(a) of that statute defines
14 what needs to be reported as defined as
15 clinical data, correct?

Witness_ Robert Dettery - Vol. 1.txt: 136:19 - 136:25

THE WITNESS: Yes.
20 BY MR. JENSEN:
21 Q. And it includes, as you can see
22 the second parenthetical,
23 epidemiological studies or analyses of
24 experience in a monitored series of
25 patients, correct?

Witness_ Robert Dettery - Vol. 1.txt: 137:2 - 137:9

THE WITNESS: That's what it
3 says.
4 BY MR. JENSEN:
5 Q. And you agree that if such a study
6 or analysis of experience occurs in
7 relation to an ANDA drug, the ANDA
8 holder needs to provide that clinical
9 data publication to the FDA, correct?

Witness_ Robert Dettery - Vol. 1.txt: 137:13 - 137:24

THE WITNESS: No.
14 BY MR. JENSEN:
15 Q. And what is the regulation upon
16 which you rely on in disagreeing with
17 that?
18 A. The 314.97, I believe, addresses
19 that to some extent, and also the FDA
20 policy.
21 Q. How do you think 314.97 in any
22 manner allows an ANDA holder to not
23 comply with what we just reviewed of
24 314.81?

Witness_ Robert Dettery - Vol. 1.txt: 138:1 - 138:8

THE WITNESS: Well, I would
2 need to see 314.97 to refresh my memory.
3 BY MR. JENSEN:
4 Q. Other than 314.97, is there any
5 other regulation that you know of that
6 you believe supports the proposition
7 that an ANDA holder need not supply such
8 clinical data to the FDA?

Witness_ Robert Dettery - Vol. 1.txt: 138:10 - 138:11

THE WITNESS: Again, only
11 that section

Witness_ Robert Dettery - Vol. 1.txt: 138:16 - 138:21

Q. Here is 314.97. And don't you
17 agree that it says nothing that any
18 plain read of that one English sentence

19 can be interpreted to mean that an ANDA
20 holder need not comply with the clinical
21 data production requirements of 314.81?

Witness_ Robert Dettery - Vol. 1.txt: 138:23 - 139:9

THE WITNESS: Well, I don't
24 know if this is the complete citation
25 for 314.97.
00139
1 BY MR. JENSEN:
2 Q. I represent to you it is, and I
3 ask you to assume for the purposes of my
4 question that it is.
5 Isn't it true that nothing in it
6 provides support for the proposition
7 that an ANDA holder need not supply
8 clinical data, as we just defined it, to
9 the FDA?

Witness_ Robert Dettery - Vol. 1.txt: 139:13 - 139:15

THE WITNESS: It says, the
14 applicant shall comply with requirements
15 of 314.70 and 314.71.

Witness_ Robert Dettery - Vol. 1.txt: 139:21 - 140:5

Q. You just told me that the
22 regulation you relied on to not have to
23 provide clinical data to the FDA was
24 314.97. Now I have shown it to you,
25 it's one sentence long.
00140
1 Isn't it true, sir, that there is
2 nothing in that sentence from which one
3 might conclude that an ANDA holder need
4 not provide such clinical data to the
5 FDA?

Witness_ Robert Dettery - Vol. 1.txt: 140:8 - 140:20

THE WITNESS: I can't
9 conclude that because this sentence
10 refers to other sections of 314.
11 BY MR. JENSEN:
12 Q. The bottom line is, you can't
13 identify any regulation upon which you
14 have ever concluded that an ANDA holder
15 need not supply clinical data as we just
16 defined it to the FDA, as we sit here
17 now, correct?
18 MR. COSGROVE: The same
19 objection.
20 THE WITNESS: No.

Witness_ Robert Dettery - Vol. 1.txt: 141:13 - 141:15

Q. Has Mutual ever done any post-
14 marketing surveillance of the medical
15 literature for sulindac?

Witness_ Robert Dettery - Vol. 1.txt: 141:19 - 142:17

THE WITNESS: I believe so.
20 BY MR. JENSEN:
21 Q. When did Mutual first do post-
22 marketing surveillance of the medical
23 literature for sulindac?
24 A. I believe it was about maybe two
25 years ago.
00142
1 Q. So why, in 2007, which is two
2 years ago, did Mutual first decide to do
3 its first surveillance of the medical
4 literature regarding sulindac?
5 A. It was not surveillance of medical
6 literature just for sulindac. As the
7 company transitioned from a generic
8 company to a branded company, we began
9 to follow the expectations and
10 obligations of a branded company and do
11 the survey of the medical literature for
12 all of our products.
13 Q. Starting in 2007, when Mutual's
14 related company first got NDA products,
15 did Mutual start surveying the medical
16 literature regarding its ANDA products
17 also?

Witness_ Robert Dettery - Vol. 1.txt: 142:20 - 142:22

THE WITNESS: We began doing
21 medical literature searches for all of
22 our products.

Witness_ Robert Dettery - Vol. 1.txt: 143:21 - 143:25

Q. Okay. So starting in 2007, when
22 Mutual's related company got NDAs,
23 Mutual started doing surveillance of the
24 medical literature regarding about 50 or
25 60 of its ANDA drugs also, correct?

Witness_ Robert Dettery - Vol. 1.txt: 144:4 - 144:9

THE WITNESS: It was around
5 2006, 2007, sometime around there.
6 BY MR. JENSEN:
7 Q. Definitely not before 2006,
8 though, correct?
9 A. Correct.

Witness_ Robert Dettery - Vol. 1.txt: 146:2 - 146:10

Do you think it's better for the
3 health of the patients who take their
4 drugs and do you think it's better for
5 the information that's potentially
6 provided to the physicians who prescribe
7 drugs, that companies survey the medical
8 literature to find out new information
9 that effects the benefit and risk
10 profile of their drugs?

Objection (146:2 to 146:14):
-402
-403
-602
-Calls for opinion
-Argumentative

Ruling: Sustained (beginning at line 141:13).

Witness_ Robert Dettery - Vol. 1.txt: 146:13 - 147:15

THE WITNESS: I really have
14 no opinion on that.
15 BY MR. JENSEN:
16 Q. Why did Mutual start surveying the
17 medical literature for its ANDA drugs in
18 2006 and 2007 just because its related
19 company was looking into or then got
20 some NDA drugs?
21 A. Well, as I said, we transitioned
22 from a generic company to a branded
23 company, and as a branded company, even
24 though we may be marketing generic
25 products, it's expected of a branded
00147
1 company to do that surveillance of the
2 literature.
3 Q. For both its NDA and ANDA drugs,
4 correct?
5 A. It's --
6 MR. COSGROVE: Objection.
7 THE WITNESS: It's expected
8 for the branded drugs, but we went over
9 above and included the generic drugs.
10 BY MR. JENSEN:
11 Q. Okay. And Mutual had never gone
12 over and above and ever surveyed the
13 medical literature for any of its ANDA
14 drugs, including sulindac, before 2006,
15 correct?

Objection (146:16 to 148:16):
-402
-403
-407 (Rx date 12/04)
-Plaintiff intentionally altered the witness' response, striking some words from his response

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: Page 148, Line 13

Before 2006

Witness_ Robert Dettery - Vol. 1.txt: Page 148, Line 14

we

Witness_ Robert Dettery - Vol. 1.txt: 148:15 - 148:16

did not
16 perform literature surveillance.

Witness_ Robert Dettery - Vol. 1.txt: 148:21 - 149:3

Q. You agree that for the 13 years,
22 between 1991 and 2004, that the
23 regulations did not prohibit you,
24 meaning Mutual, from doing what it now
25 you say chooses to do for its ANDA
00149
1 drugs, which is survey the medical
2 literature?
3 Nothing prohibited that, correct?

Objection (148:21 to 149:16):
-Seeks legal opinion

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: Page 149, Line 16

THE WITNESS: I don't know.

Witness_ Robert Dettery - Vol. 1.txt: 150:5 - 150:13

As a regulatory professional, who
6 knows the regulations or should know the
7 regulations, isn't it correct that you
8 can't identify any regulation which
9 prohibited Mutual, in those 13 years,
10 from doing what it now chooses to do as
11 it says for some of its ANDA drugs and
12 survey the medical literature?
13 Isn't that true?

Objection (150:5 to 150:16):
-402
-403 (not relevant to adequacy of warning)
-Compound
-Vague
-Seeks legal opinion

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 150:16 - 150:23

THE WITNESS: Correct.
17 BY MR. JENSEN:
18 Q. Does Mutual, after 2006 or '07,
19 now provide the FDA for the 50 or 60 of
20 its ANDA drugs that it surveys the
21 medical literature for some of that
22 medical literature when it deems it
23 reportable?

Objection (150:18 to 151:22):
-402
-403 (not relevant to whether 2004 warning was adequate)
-407

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 150:25 - 151:9

THE WITNESS: Yes.
00151
1 BY MR. JENSEN:
2 Q. And when I just referenced the
3 clinical studies section there in the
4 parenthetical about epidemiological
5 studies or following a monitored series
6 of patients, is that exactly the type of
7 medical literature that Mutual would now
8 provide the FDA for 50 or 60 of its ANDA
9 drugs?

Witness_ Robert Dettery - Vol. 1.txt: 151:14 - 151:22

THE WITNESS: Yes, I really
15 don't know.
16 BY MR. JENSEN:
17 Q. Well, aren't you the one at Mutual
18 who makes the call of what's
19 reportable? Ultimately, you are where
20 the buck stops?
21 A. I'm the head of the department
22 that makes that decision.

Witness_ Robert Dettery - Vol. 1.txt: 152:17 - 153:4

Q. Isn't it true that the ultimate
18 decision as to whether something gets
19 reported or not, in an annual report or
20 a periodic report, there's an issue at
21 Mutual, you are the final word on that
22 because you are the head of regulatory
23 affairs, correct?
24 A. Yes.
25 Q. And you agree, as the head of
00153
1 regulatory affairs, that epidemiological

Objection (152:17 to 154:10):
-402
-403
-407

Ruling: Sustained.

2 studies or monitored series of patients
3 must be reported pursuant to the
4 literature we just looked at, right?

Witness_ Robert Dettery - Vol. 1.txt: 153:7 - 153:9

THE WITNESS: If it provides
8 new information on serious and
9 unexpected events, then yes.

Witness_ Robert Dettery - Vol. 1.txt: 153:20 - 153:23

Q. Isn't it true that Mutual provides
21 such information now to the FDA on its
22 ANDA products that it markets and
23 distributes like sulindac?

Witness_ Robert Dettery - Vol. 1.txt: 153:25 - 154:7

THE WITNESS: Well, like I
00154
1 said, we do the literature searches in
2 the medical literature, and if something
3 needs to be reported, we will report it.
4 BY MR. JENSEN:
5 Q. Including that example, right, an
6 epidemiological study that monitored a
7 series of patients, correct?

Witness_ Robert Dettery - Vol. 1.txt: 154:9 - 154:10

THE WITNESS: If it results
10 in a serious and unexpected event.

Witness_ Robert Dettery - Vol. 1.txt: 154:20 - 154:24

Q. Is Mutual now a more responsible
21 company as pertains to its 50 or 60 ANDA
22 drugs now that it surveys the medical
23 literature and reports it when
24 appropriate to the FDA?

Objection (154:20 to 155:6):
-402
-403
-407
-Seeks improper opinion
-Argumentative

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 155:4 - 155:6

THE WITNESS: Well, you are
5 asking me for an opinion. I can't -- I
6 have no opinion on that.

Witness_ Robert Dettery - Vol. 1.txt: 157:23 - 158:5

Q. Don't you agree, Mr. Dettery, that
24 it is more responsible for drug
25 companies and in the best and better
00158
1 interest of patients and their
2 physicians when they survey the medical
3 literature and report it as appropriate
4 as Mutual has chosen to do since about
5 '06 or '07 and did not do before that?

Objection (157:23 to 159:24):
-402
-403
-407
-602
-Calls for opinion

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 158:8 - 158:18

THE WITNESS: Again, I can't
9 answer that. That calls for an
10 opinion. I really have no opinion on
11 that.
12 BY MR. JENSEN:
13 Q. Well, if you don't have an opinion
14 on that and you are the top regulatory
15 person at Mutual, please tell the jury
16 why in '06 or '07 Mutual decided to
17 start doing this for their ANDA drugs
18 that it distributes?

Witness_ Robert Dettery - Vol. 1.txt: 158:24 - 159:18

THE WITNESS: I think I
25 already told you that we became a
00159
1 branded company, and we -- as branded
2 companies are obligated to do, then we
3 began to do the literature searches.
4 BY MR. JENSEN:
5 Q. But that's really a distinction
6 that makes no difference as it pertains
7 to the ANDA drugs.
8 Just, if there is a reason, please
9 tell this jury why it was a good reason
10 for Mutual to start on its ANDA drugs
11 surveying the medical literature and
12 reporting that it was appropriate,
13 forgetting about the fact that you
14 became a branded company. I'm
15 suggesting, so what?
16 I'm suggesting please tell the
17 jury why it's better that you do that
18 now for your generic drugs.

Witness_ Robert Dettery - Vol. 1.txt: 159:20 - 159:24

THE WITNESS: I'm saying the
21 reason we began doing it for generic
22 drugs is because we began doing it for
23 all of our products once we became a
24 branded company.

Witness_ Robert Dettery - Vol. 1.txt: 160:1 - 160:13

Q. If you would flip to Exhibit 13 in
2 here, sir. In there.
3 And that's a publication in the
4 Journal of Rheumatology in 2003, as you
5 can see from the bottom, correct?
6 A. Yes.
7 Q. And it's a publication entitled
8 "The Risk of" -- I will abbreviate --
9 "SJS and TEN from NSAIDs, a
10 Multinational Perspective." Correct?
11 A. That's what it says.
12 Q. And sulindac is an NSAID, right?
13 A. Yes.

Objection (160:1 to 164:16):
-Improper publishing
-Improper examination of lay witness on scientific literature
-602
-702
-Speculation

Ruling: Sustained. Mutual's notice of the Mockenhaupt study is no longer relevant, since Bartlett's negligence and failure-to-warn claims have been dismissed.

Witness_ Robert Dettery - Vol. 1.txt: 160:15 - 160:19

At least we know from the title that
16 this article is about the relationship
17 or not between these deadly skin
18 diseases and NSAIDs, and sulindac is an
19 NSAID. Fair?

Witness_ Robert Dettery - Vol. 1.txt: 160:22 - 161:3

THE WITNESS: What you asked
23 is correct, yes.
24 BY MR. JENSEN:
25 Q. Okay. And this was published the
00161
1 year before Karen Bartlett was
2 prescribed sulindac, she was prescribed
3 it at the end of 2004, correct?

Witness_ Robert Dettery - Vol. 1.txt: 161:6 - 161:7

THE WITNESS: I don't know
7 when she was prescribed sulindac.

Witness_ Robert Dettery - Vol. 1.txt: 161:10 - 161:19

I'm asking you to assume she was
11 prescribed it December 30, 2004, which
12 was the year after this was published,
13 correct?
14 A. This was published 2003, so...
15 Q. Okay. And if we flip to Page 3 of
16 the medical publication, it has a table
17 there and it lists many NSAIDs and some
18 other drugs and their multivariate
19 relative risks, correct?

Witness_ Robert Dettery - Vol. 1.txt: 161:22 - 162:6

THE WITNESS: I can only read
23 from the page, and that's what it says.
24 BY MR. JENSEN:
25 Q. Thank you, sir.
00162
1 And the other NSAID category,
2 if you follow across, has a cross there,
3 and that cross is a footnote, and that
4 footnote defines the other NSAID group
5 as a number of NSAIDs, which includes
6 sulindac, correct?

Witness_ Robert Dettery - Vol. 1.txt: 162:9 - 162:17

THE WITNESS: That's what it
10 says.
11 BY MR. JENSEN:
12 Q. And in the next table down, under
13 the Other NSAIDs, when taken for less
14 than or equal to eight weeks, it reports
15 a relative risk of 4.5 to a
16 statistically significant degree,
17 correct?

Witness_ Robert Dettery - Vol. 1.txt: 162:20 - 163:4

THE WITNESS: That's what it
21 says.
22 BY MR. JENSEN:
23 Q. And you understand, do you not,
24 that this publication the year before
25 Karen was prescribed this drug was
00163
1 reporting that this group of other
2 NSAIDs has a 450 percent greater
3 likelihood of resulting in SJS and TEN
4 than the background rate, correct?

Witness_ Robert Dettery - Vol. 1.txt: 163:9 - 163:16

THE WITNESS: I can't agree
10 to that.
11 BY MR. JENSEN:
12 Q. Is the reason you can't agree to
13 that is because you don't have an
14 understanding of the relationship
15 between a relative risk of 4.5 and a 400
16 percent greater risk? Is that fair?

Witness_ Robert Dettery - Vol. 1.txt: 163:18 - 163:24

THE WITNESS: Yes.
19 BY MR. JENSEN:
20 Q. So the reason you can't say that
21 is because you are not clear whether
22 that is true or not from a statistic
23 standpoint, not that you are denying
24 it's true. Fair?

Witness_ Robert Dettery - Vol. 1.txt: 164:1 - 164:3

THE WITNESS: I'm not denying
2 it is written on this piece of paper.
3 That's all I can testify to.

Witness_ Robert Dettery - Vol. 1.txt: 164:6 - 164:12

And this multinational study of
7 NSAIDs, which include two reports of
8 sulindac, is the precise type of
9 clinical data that starting in '06 or
10 '07 that Mutual would have provided to
11 the FDA for its ANDA drugs, including
12 sulindac, correct?

Witness_ Robert Dettery - Vol. 1.txt: 164:15 - 164:16

THE WITNESS: Not
16 necessarily.

Witness_ Robert Dettery - Vol. 1.txt: 164:24 - 165:2

Q. Your interpretation of 314.81 is
25 that epidemiological studies only need
00165
1 be reported when they have -- relate to
2 unexpected, unlabeled events?

Objection (164:24 to 165:13):
-402
-403
-Calls for legal opinion

Ruling: Sustained. The witness may not testify about the meaning of FDA regulations.

Witness_ Robert Dettery - Vol. 1.txt: 165:6 - 165:7

Q. That's what you have twice said,
7 right?

Witness_ Robert Dettery - Vol. 1.txt: 165:10 - 165:13

THE WITNESS: Yes. My
11 understanding is the literature to be
12 reported is for serious and unexpected
13 events.

Witness_ Robert Dettery - Vol. 1.txt: 167:11 - 167:16

There is
12 nothing in the text of 314.81 that
13 limits the need to report clinical data,
14 such as epidemiological studies, to ones
15 that are not in the label or not
16 expected. Isn't that true?

Objection (167:11 to 168:11):
-402
-403
-Calls for legal opinion

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: Page 168, Line 11

THE WITNESS: That's correct.

Witness_ Robert Dettery - Vol. 1.txt: 169:12 - 169:23

Isn't it true the only effect of
13 the distinction that you were talking
14 about, which has nothing to do with
15 whether you provide clinical data or
16 not, whether an event is expected or
17 unexpected, meaning labeled or
18 unlabeled, the only effect of that is
19 that you don't need to give adverse
20 events on a 15-day basis to the FDA, if
21 they are in the label, then they don't
22 need to be provided on a 15-day basis?
23 Isn't that true?

Objection (169:12 to 171:17):
-402
-403
-Calls for legal opinion
-Improper publishing

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 170:1 - 170:2

THE WITNESS: That part is
2 true about it being a 15-day report.

Witness_ Robert Dettery - Vol. 1.txt: 170:5 - 170:24

Back to Exhibit 362, which is
6 314.80. Tell me when you are there.
7 A. Okay.
8 Q. Page 5, the letter I. Can you
9 read me where it says Recordkeeping,
10 please.
11 A. Yes. You want me to read it?
12 Q. Please.
13 A. "Recordkeeping: The applicant
14 shall maintain for a period of ten years
15 records of all adverse drug experiences
16 known to the applicant, including raw
17 data and any correspondence relating to
18 adverse drug experiences."

19 Q. And, first, for the words used, a
20 drug company remains an applicant after
21 they are selling their product, for ten
22 or 20 or 30 years they are still
23 considered an applicant in these
24 regulations, correct?

Witness_ Robert Dettery - Vol. 1.txt: 171:1 - 171:7

THE WITNESS: Yes.
2 BY MR. JENSEN:
3 Q. Right. Because an NDA or an ANDA
4 is a living document, even after
5 approval occurs, you still file stuff
6 with the application, whether it be an
7 abbreviated one or a new one, correct?

Witness_ Robert Dettery - Vol. 1.txt: 171:9 - 171:14

THE WITNESS: That's correct.
10 BY MR. JENSEN:
11 Q. So when they are talking about
12 applicant here, you understand that's
13 talking about drug companies whether
14 pre-approval or post-approval. Fair?

Witness_ Robert Dettery - Vol. 1.txt: 171:16 - 171:17

THE WITNESS: Yes. That's my
17 definition of an applicant, yes.

Witness_ Robert Dettery - Vol. 1.txt: 176:2 - 176:11

Q. And what is Exhibit 365,
3 Mr. Dettery?
4 A. It is the -- our complaint file
5 for medical complaint No. 08035.
6 Q. And who is the patient for that
7 complaint?
8 A. Karen Bartlett.
9 Q. Does all of 365 pertain to Karen
10 Bartlett's adverse reactions, SJS, TEN,
11 blindness, coma, to sulindac?

Objection (176:2 to 177:13):
-402
-403
-407
-602
- Handling of plaintiff's complaint file has no bearing on this case

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 176:14 - 177:3

THE WITNESS: Well, the file
15 is our investigation into the reported
16 side effects that were provided to us in
17 the notification of this lawsuit.
18 BY MR. JENSEN:
19 Q. Okay. But, obviously, you have
20 all Karen's medical records, and so you
21 know that she has generally been blind
22 in both eyes for the last four years,
23 she was in a medically protective coma
24 for weeks on end, she has had esophageal
25 dilatation because she had an esophageal
00177
1 stricture.
2 Have all those records been
3 provided to the FDA?

Witness_ Robert Dettery - Vol. 1.txt: 177:11 - 177:13

A. I don't know specifically. I
12 wasn't directly involved in what was
13 submitted to FDA.

Witness_ Robert Dettery - Vol. 1.txt: 180:14 - 180:22

Q. And how long has Mutual been
15 utilizing Prosar to analyze adverse
16 reactions reported to it?
17 A. Since about 2005.
18 Q. Definitely not in 2004?
19 A. No.
20 Q. Does Prosar also survey the
21 medical literature on Mutual's behalf
22 since 2006 or 2007?

Objection (180:14 to 181:10):
-402
-403
-407 (Rx date 12/04)

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 180:25 - 181:5

THE WITNESS: Yes.
00181
1 BY MR. JENSEN:
2 Q. It's still Mutual's
3 responsibility, but Prosar is Mutual's
4 agent which does that, provides those
5 services for it, correct?

Witness_ Robert Dettery - Vol. 1.txt: 181:9 - 181:10

THE WITNESS: Well, Prosar is
10 our agent. When

Witness_ Robert Dettery - Vol. 1.txt: 184:1 - 184:14

Q. Exhibit 303, sir. Tell me when
2 you are there.
3 A. 303?
4 Q. Yes, sir.
5 Is that the document that
6 authorized Mutual to start manufacturing
7 and distributing sulindac?
8 A. Yes.
9 Q. And Mutual is reminded to comply
10 with 314.80 and 314.81 of the
11 regulations, which are the very
12 regulations that you and I have spoken
13 about today, correct?
14 A. Yes.

Objection:
-402
-403 (state causes of action are not based upon compliance with federal regulations)

Ruling: Sustained as to lines 184:9 through 184:14. Otherwise overruled.

Witness_ Robert Dettery - Vol. 1.txt: 188:1 - 188:3

Q. And did you review 367, these
2 Answers to Interrogatories, before they
3 were produced, sir?

Objection (188:1 to 189:2):
-Improper impeachment

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 188:9 - 188:10

THE WITNESS: I don't recall
10 if I saw this before or not.

Witness_ Robert Dettery - Vol. 1.txt: 188:15 - 189:2

And do you see
16 Interrogatory No. 6.
17 A. Yes.
18 Q. And it says, "Do you contend,"
19 and, of course, you is not a reference
20 to Robert Dettery, it's a reference to
21 Mutual, because that's who it is served
22 to.
23 It says, "Do you contend that
24 sulindac cannot cause SJS or TEN?" And
25 the answer is "No."
00189
1 Do you see that?
2 A. That's what it says, yes.

Witness_ Robert Dettery - Vol. 1.txt: 190:12 - 190:15

Q. Mutual has a label for its
13 sulindac product that says SJS and TEN
14 are caused by sulindac. Does Mutual
15 agree that label is true and accurate?

Objection (190:12 to 190:20):
-Misleading (no such label statement)

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 190:18 - 190:20

THE WITNESS: As far as I
19 know, our labeling is as true and as
20 accurate as we can make it.

Witness_ Robert Dettery - Vol. 1.txt: 192:13 - 192:20

You see that Interrogatory 13 asks
14 whether or not Mutual had ever done any
15 safety analyses or reviews or safety
16 signal or pharmacovigilance analyses or
17 reviews for serious skin reactions
18 relating to sulindac, and it says none.
19 Do you understand that to be
20 true?

Objection (192:13 to 192:23):
-Improper impeachment

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 192:23 - 193:12

THE WITNESS: Yes.
24 BY MR. JENSEN:
25 Q. And now go to Page 12. Tell me
00193
1 when you are there.
2 A. Page 12?
3 Q. Yes, sir.
4 And does the answer -- just the
5 answer reads, "Mutual responds that it
6 did not conduct routine scientific
7 literature searches for sulindac
8 products between 1990 and the date of
9 plaintiff's prescription."
10 Representing to you that was 2004,
11 you know that to be true as well,
12 correct?

Objection (192:25 to 193:14):
-Improper impeachment

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: Page 193, Line 14

THE WITNESS: Correct.

Witness_ Robert Dettery - Vol. 1.txt: 194:10 - 194:15

Q. You know that Mutual never
11 distributed or made any advocacy to
12 distribute a medication guide or a
13 patient insertion leaflet or a document
14 designed for the patient to read before
15 2004, correct?

Objection (194:10 to 194:18):
-402
-403 (no such duty under New Hampshire law - duty to warn learned intermediary)

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: Page 194, Line 18

THE WITNESS: That's correct.

Witness_ Robert Dettery - Vol. 1.txt: 200:5 - 200:8

Do you agree that Mutual has
6 always had the ability since the day
7 after sulindac was approved to suspend
8 sales or take sulindac off the market?

Objection (200:5 to 200:10):
-402
-403 (no such duty under New Hampshire law - duty to warn learned intermediary)

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: Page 200, Line 10

THE WITNESS: Yes.

Witness_ Robert Dettery - Vol. 1.txt: 200:12 - 200:14

Q. Do you agree that Mutual has
13 always had the ability to do CBE label
14 changes?

Witness_ Robert Dettery - Vol. 1.txt: 200:16 - 201:9

THE WITNESS: No.
17 BY MR. JENSEN:
18 Q. Is a CBE label change something
19 that stands for changes being effected?
20 A. That's correct.
21 Q. And a changes being effected label
22 changes can be for minor things, like
23 dosage or administration, or they can be
24 for major things, like enhancing or
25 strengthening warnings, correct?
00201
1 A. No.
2 Q. Okay. What is your definition of
3 changes being effected label changes?
4 A. The regulations permit the brand
5 companies to change their labeling to
6 include newly acquired information that
7 shows a causal relationship between
8 their product and whatever information
9 they have.

Objection (200:18 to 201:9):
-402
-403
-Calls for legal opinion

Ruling: Sustained (beginning at line 200:12).

Witness_ Robert Dettery - Vol. 1.txt: 203:23 - 203:25

Q. 314.97, as you understand it,
24 applies to ANDA products whether they
25 are RLDs or not, correct?

Objection (203:23 to 204:9):
-402
-403
-Calls for legal opinion

Ruling: Sustained as to lines 203:23 through 204:5. Otherwise overruled.

Witness_ Robert Dettery - Vol. 1.txt: 204:2 - 204:14

THE WITNESS: It says,
3 changes for approved abbreviated
4 applications, so I would agree with
5 that.
6 BY MR. JENSEN:
7 Q. And an RLD is the referenced
8 listed drug, correct?
9 A. Right.
10 Q. Are any of the Mutual's ANDAs
11 designated RLDs?
12 A. Yes.
13 Q. Which drugs, please, in which
14 form?

Objection (204:10 to 204:25):
-402

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 204:17 - 205:14

THE WITNESS: Quinidine
18 gluconate extended-release tablets.
19 BY MR. JENSEN:
20 Q. When did Mutual become the RLD for
21 that extended-release drug?
22 A. Are you asking me like what year?
23 Q. Best approximation.
24 A. Approximately seven, eight years
25 ago.
00205
1 Q. Okay. When did Mutual first start
2 doing surveying of the medical
3 literature and potentially reporting
4 what it found and deemed appropriately
5 reportable for that drug in that
6 extended-release form?
7 A. About two years ago.
8 Q. So, hence, is it correct to state
9 that even after Mutual became the
10 reference listed drug for quinidine, it
11 did not start surveying the literature
12 until approximately three or four years
13 after it became the reference listed
14 drug?

Objection (205:1 to 206:6):
-402
-403
-407 (occurred after 12/04)

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 205:17 - 205:23

THE WITNESS: That's correct.
18 BY MR. JENSEN:
19 Q. So, I take it, you did not see a
20 cause-and-effect relationship between
21 being designated the RLD and having to
22 start surveying the literature
23 immediately. Fair?

Witness_ Robert Dettery - Vol. 1.txt: 206:2 - 206:6

THE WITNESS: Yes.
3 BY MR. JENSEN:
4 Q. Yes, that's true, you didn't think
5 one related to the other?
6 A. Yes.

Witness_ Robert Dettery - Vol. 1.txt: 208:25 - 209:25

Q. Approximately how many times has
00209
1 Mutual suspended the sales of or
2 withdrawn an application to stop selling
3 an ANDA drug?
4 A. Well, suspended sales happened
5 several times, and withdrawing an
6 application happened once, that I
7 remember.
8 Q. And for the benefit of the jury,
9 is withdrawing an application the same
10 thing as telling the FDA you are no
11 longer going to distribute or market
12 this drug?
13 Does it have that effect?
14 A. No.
15 Q. Okay. Tell us what withdrawing an
16 application means, then, to you.
17 A. Withdrawing an application means
18 that you are basically doing away with
19 your application and you will not market
20 that product in the future because your
21 application no longer exists.
22 Q. Is what I said right, then, that
23 when you withdraw an application, you
24 can no longer sell the drug, right?
25 A. Yes.

Objection:
-402
-403

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 1.txt: 212:17 - 212:22

Q. Has Mutual ever advocated to the
18 FDA, between, let's pick years, 1991 and
19 2004, that it be permitted to make a
20 change as being effected label change to
21 add to or increase risk information or
22 warning information?

Objection (212:17 to 213:22):
-402
-403
-Vague
-Ambiguous

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 213:1 - 213:7

THE WITNESS: Between 1991
2 and 2004?
3 BY MR. JENSEN:
4 Q. Yes, sir.
5 A. No.
6 Q. Has Mutual at any time before 1991
7 ever so advocated?

Witness_ Robert Dettery - Vol. 1.txt: 213:10 - 213:16

THE WITNESS: Not to my
11 knowledge.
12 BY MR. JENSEN:
13 Q. Has Mutual ever advocated to the
14 FDA that all of the labels be changed
15 for a given drug, such as sulindac, at
16 any time between 1991 and 2004?

Witness_ Robert Dettery - Vol. 1.txt: 213:19 - 213:22

BY MR. JENSEN:
20 Q. To add to or strengthen warning or
21 risk information?

22 A. No.

Witness_ Robert Dettery - Vol. 1.txt: 214:16 - 215:6

Q. Okay. And which drug did Mutual
17 advocate for a label change to add to or
18 strengthen warnings?
19 A. Our product Qualaquin.
20 Q. And what additional or enhanced
21 risk information did Mutual advocate for
22 Qualaquin?
23 A. We submitted a CBE to strengthen
24 the warnings for thrombocytopenia.
25 Q. And tell us what thrombocytopenia
00215
1 is, please.
2 A. My understanding, and, again, I'm
3 not a physician, my understanding is a
4 hematological disorder, meaning the
5 blood, where the person tends to bleed
6 under the skin I think.

Objection:
-402
-403 (NDA product)
-407
-702
-Calls for medical opinion

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 216:1 - 216:4

Did Mutual do a CBE
2 label change before the FDA approved the
3 label change for thrombocytopenia?
4 A. Yes.

Objection:
-402
-403 (NDA product)
-407

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 216:21 - 217:21

Q. Chronologically speaking, tell us
22 what happened.
23 A. Okay. Going how far back?
24 Q. From Mutual's determination that
25 new risk or enhanced risk information
00217
1 needed to be in the Qualaquin label.
2 A. Okay. We determined that the
3 warnings -- or the information about
4 thrombocytopenia needed to be
5 strengthened in the insert, so we
6 submitted that in June 2009 as a CBE
7 supplement.
8 And at the same time, we submitted
9 a prior approval supplement to do
10 additional labeling changes, such as
11 adding a med guide to the labeling that
12 cannot be submitted as a CBE, so we
13 submitted that as a prior approval
14 supplement.
15 So the changes that were submitted
16 under the CBE, since it went into June,
17 30 days went by, FDA did not tell us not
18 to make it effective, so it became
19 effective. It has not yet officially
20 been approved by FDA, but it is
21 effective.

Objection (216:21 to 217:24):
-402
-403 (NDA product)
-407

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 217:23 - 217:24

A. And the prior approval supplement

24 has not yet been approved.

Witness_ Robert Dettery - Vol. 1.txt: 218:21 - 219:3

Q. And is it correct to state that
22 you understand what happens is, when
23 Mutual took it upon itself to make the
24 label change to enhance the risk
25 information for this drug, is that if
00219
1 the FDA did not do anything within 30
2 days, like reject the proposed change,
3 it became effective at that time?

Objection (218:21 to 221:4):
-402
-403 (NDA product)
-407

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 219:7 - 219:13

THE WITNESS: Yes.
8 BY MR. JENSEN:
9 Q. Hence, because we are in August
10 2009, Mutual's unilateral -- defining
11 unilateral as before it was approved by
12 the FDA -- Mutual's unilateral label
13 change is now effective, correct?

Witness_ Robert Dettery - Vol. 1.txt: 219:17 - 219:22

THE WITNESS: Correct.
18 BY MR. JENSEN:
19 Q. What was the increased or enhanced
20 safety information Mutual found it
21 appropriate to make this label change
22 for? Tell us, please.

Witness_ Robert Dettery - Vol. 1.txt: 219:24 - 221:4

THE WITNESS: We became aware
25 of a number of adverse events in which
00220
1 the patient reported -- or the
2 information that was reported to us
3 claim that the patient suffered
4 thrombocytopenia or some type of a
5 relate blood disorder.
6 BY MR. JENSEN:
7 Q. How many parts of thrombocytopenia
8 or a related blood disorder did Mutual
9 receive before it determined that a
10 label needed to be changed by its own
11 action?
12 A. I don't recall the exact number.
13 Q. What's your best estimate?
14 A. There may have been about -- there
15 may have been about 30.
16 Q. And in how many years were these
17 30 received, approximately? The
18 approximate 30.
19 A. Well, they covered a time span
20 going back into the 1990s.
21 Q. Okay. So in the 1990s, we are
22 talking 15 or so years that 30
23 thrombocytopenia or related blood
24 disorder reports had been received?

25 A. Well, we received them all at the
00221
1 same time, but the reports were from --
2 covering a period back into 1990, which,
3 of course, predates our approval of our
4 NDA.

Witness_ Robert Dettery - Vol. 1.txt: 221:10 - 221:19

Q. Tell me then why approximately 30
11 were received by Mutual at the same
12 time, even though they dated for many
13 years back, 15 or so?
14 A. It was a lawsuit. We were
15 informed of a lawsuit.
16 Q. And the adverse reaction
17 information came from information
18 learned as a result of this lawsuit?
19 MR. COSGROVE: Objection.

Objection (221:10 to 222:2):
-402
-403 (NDA, other litigation)
-407

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 221:20 - 222:2

THE WITNESS: Yes.
21 BY MR. JENSEN:
22 Q. Was the lawsuit on behalf of the
23 approximate 30 or so persons?
24 A. The lawsuit was on behalf of a
25 number of people. I don't remember the
00222
1 exact number. I think there were more
2 than 30.

Witness_ Robert Dettery - Vol. 1.txt: 222:24 - 223:3

Q. Is Mutual presently waiting for
25 its prior approval supplement of the
00223
1 medication guide for Qualaquin to be
2 approved?
3 A. Yes.

Objection:
-402
-403 (NDA product)
-407

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 223:12 - 224:1

Q. Was thrombocytopenia mentioned
13 anywhere in the Qualaquin label before
14 Mutual learned of these cases through
15 this lawsuit?
16 A. Yes.
17 Q. Was it in the adverse reaction
18 section?
19 A. If I remember correctly, it was in
20 more than one section.
21 Q. Was thrombocytopenia or related
22 blood disorders in the Warnings section
23 of the Qualaquin label before Mutual
24 learned of this lawsuit and these
25 approximate 30 cases?
00224
1 A. If I remember correctly, it was.

Objection:
-402
-403 (NDA product)
-407

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 224:14 - 225:5

Tell me what Mutual put in the
15 label through its unilateral action
16 before getting FDA approval that wasn't
17 in there.
18 A. We moved it -- we expanded on the
19 statement about the warning -- warning
20 regarding the possibility of
21 thrombocytopenia, and we also moved it
22 to the top or the beginning of the
23 Warnings section, rather than it was
24 about halfway in the Warnings section
25 previously.
00225
1 Q. Is the reason Mutual moved the
2 location within the Warnings section
3 about the possibility of
4 thrombocytopenia so it would be more
5 obvious and more striking to the reader?

Objection (224:14 to 226:5):
-402
-403 (NDA product)
-407

Ruling: Sustained as to lines 224:14 through 225:12 and as to lines 225:21 through 226:5. Otherwise overruled.

Witness_ Robert Dettery - Vol. 1.txt: 225:9 - 226:1

THE WITNESS: Well, we moved
10 it to the beginning just to make it more
11 prominent.
12 BY MR. JENSEN:
13 Q. And when you make things more
14 prominent, that is an attempt to get
15 people to take notice more easily and
16 readily. Fair?
17 That's why you move it, right?
18 A. Yes.
19 Q. Is that fair?
20 A. Yes.
21 MR. COSGROVE: Objection.
22 BY MR. JENSEN:
23 Q. So, you agree, based upon that
24 action you just took two months ago,
25 that where things are in a label are
00226
1 important? Fair?

Witness_ Robert Dettery - Vol. 1.txt: Page 226, Line 5

THE WITNESS: Yes.

Witness_ Robert Dettery - Vol. 1.txt: 228:21 - 229:5

Is Mutual's Qualaquin changes
22 being effected to enhance or add to
23 warning information for a serious
24 adverse reaction the first time, to your
25 knowledge, when they did it in June
00229
1 2009, that the company had ever done it
2 for any drug, NDA or ANDA?
3 MR. COSGROVE: Objection.
4 Form.
5 THE WITNESS: Yes.

Objection (228:21 to 232:5):
-402
-403 (NDA product)
-407

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 229:11 - 230:8

Q. Before Mutual decides to initially

12 file and initially become an applicant,
13 pre-approval obviously, for an ANDA
14 product, does it assess the risk and
15 benefit profile of the product in
16 relation to the product's label?
17 A. What do you mean by assess?
18 Q. I mean make an assessment of
19 whether they believe that the product
20 label as it presently exists for other
21 participants in the market of that drug
22 is a proper reflection of the risk and
23 benefit profile.
24 Obviously, I know they don't have
25 access to the data, the clinical or
00230
1 preclinical trials of the RLD.
2 Obviously, what that assess would entail
3 is a review of the medical literature
4 and an assessment in that regard.
5 So, does Mutual do an assessment
6 of the accuracy of the label for an ANDA
7 drug before it decides to file an ANDA
8 application for a drug?

Witness_ Robert Dettery - Vol. 1.txt: 230:12 - 231:6

THE WITNESS: No.
13 BY MR. JENSEN:
14 Q. To your knowledge, Mr. Dettery,
15 did anyone at Mutual ever do an
16 assessment of serious skin reactions,
17 including, of course, SJS and TEN, in
18 relation to sulindac before learning of
19 Karen Bartlett?
20 A. Not to my knowledge.
21 Q. Let me expand my question.
22 To your knowledge, did Mutual ever
23 do an assessment of severe skin
24 reactions, including, of course, SJS and
25 TEN, in relation to any NSAID or Bactrim
00231
1 before learning of Karen Bartlett --
2 MR. COSGROVE: Objection.
3 BY MR. JENSEN:
4 Q. -- i.e., the association of such
5 reactions, obviously, in any of its
6 drugs?

Witness_ Robert Dettery - Vol. 1.txt: 231:8 - 231:23

THE WITNESS: To my
9 knowledge, we haven't done any
10 assessment of the type that you are
11 describing.
12 BY MR. JENSEN:
13 Q. After Mutual learned of Karen
14 Bartlett's SJS and TEN and over a
15 hundred days hospitalization, weeks,
16 perhaps months, of being in a medically
17 protective coma, doctors' conclusions
18 that for most of the last five years she
19 has been legally blind in both eyes,

20 after nine or ten surgeries now, what
21 has Mutual done to assess the
22 relationship between sulindac and SJS
23 and TEN?

Witness_ Robert Dettery - Vol. 1.txt: 232:2 - 232:5

THE WITNESS: Well, as I
3 stated previously, we now do literature
4 searches, and anything that would show
5 up there would be assessed.

Witness_ Robert Dettery - Vol. 1.txt: 241:4 - 241:13

And is that a changes being
5 effected for number of tablets in a
6 bottle?
7 A. Yes.
8 Q. And that's pursuant to the same
9 general provisions as was utilized on
10 behalf of the NDA drug Qualaquin to make
11 CBE label changes. They are, obviously,
12 different sections, but it's part of the
13 same 314.70, correct?

Objection (241:4 to 244:1): -402

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 241:16 - 241:20

BY MR. JENSEN:
17 Q. They are both changes being
18 effected, and changes being effected
19 both emanate from the same regulation,
20 which is 314.70, correct?

Witness_ Robert Dettery - Vol. 1.txt: 241:23 - 243:3

THE WITNESS: They are both,
24 yes, special supplements changes being
25 effected.
00242
1 BY MR. JENSEN:
2 Q. Please refer to Exhibit 317. Tell
3 me when you are there.
4 That also is a special supplement
5 changes being effected by Mutual,
6 correct?
7 A. Yes.
8 Q. And that is for moisture
9 specifications, correct?
10 A. Yes, it is.
11 Q. And Exhibit 320 is the FDA's
12 response letter telling you that that
13 changes being effected proposal was
14 deficient, correct?
15 A. Yes.
16 Q. What is Exhibit 321, please?
17 A. 321 is the summary report of the
18 stability data for several different
19 lots of sulindac.
20 Q. Okay. And, again, does this
21 pertain to the 24 versus 36 months, how
22 long you can keep it issue?
23 A. Yes, it pertains to it. Sure.

24 Q. Was this an analysis to see
25 whether or how or on what basis Mutual
00243
1 might again try to increase how long it
2 can keep the drug before it had to
3 dispose of it up to three years?

Witness_ Robert Dettery - Vol. 1.txt: 243:6 - 244:1

THE WITNESS: Well, I don't
7 know if you would call this an
8 analysis. This is a summary of the
9 results.
10 BY MR. JENSEN:
11 Q. And this is dated July of '01,
12 correct? I see by a signature down
13 there, the first page.
14 A. Yes.
15 Q. And is there any way to tell from
16 this document where any of these batch
17 shipments went? For example, were
18 they -- strike that.
19 Does Mutual have a way of going
20 back and determining, from any
21 information, what batches shipped what
22 sulindac product where, or what batches
23 went to where?
24 A. We have distribution records that
25 would show where specific lots were
00244
1 sent.

Witness_ Robert Dettery - Vol. 1.txt: 246:6 - 246:11

BY MR. JENSEN:
7 Q. So far we have reviewed changes
8 being effected submissions by Mutual for
9 how many tablets could go in a bottle
10 and the moisture of the product and
11 where the supplier might be, correct?

Objection (246:6 to 246:15):
-402

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: Page 246, Line 15

THE WITNESS: Yes.

Witness_ Robert Dettery - Vol. 1.txt: 247:6 - 247:14

Q. Do you agree that it is more
7 important to patients and physicians
8 that they have the most current risk
9 information regarding risks, such as SJS
10 and TEN and coma and blindness, as
11 opposed to these supplemental changes
12 being effected, which address matters of
13 where the product is produced or
14 moisture specifications?

Objection (247:6 to 247:25):
-402
-403
-602
-Improper lay witness opinion
-Argumentative

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 247:18 - 247:25

THE WITNESS: No, I don't
19 necessarily agree with that.
20 BY MR. JENSEN:

21 Q. Obviously, physicians want to make
22 sure the product is produced properly.
23 That's your point, correct?
24 A. Yes. They want to make sure the
25 product is not adulterated in any way.

Witness_ Robert Dettery - Vol. 1.txt: 248:19 - 249:3

What's more important to
20 physicians and patients, in your view,
21 having done this for over two decades
22 like you have, to have updated risk
23 information regarding deadly diseases,
24 like SJS and TEN, and risks, like coma
25 and blindness, or where the product
00249
1 might be produced, presuming it is going
2 to be just as well produced in either of
3 two places?

Objection (248:19 to 249:10):
-402
-403
-602
-Improper lay witness opinion
-Argumentative

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 249:6 - 250:2

THE WITNESS: Well, you are
7 asking me what's important to
8 physicians. I don't -- I'm not a
9 physician. I don't know how to answer
10 that.
11 BY MR. JENSEN:
12 Q. Exhibit 328 is a fourth example of
13 a special supplement label change under
14 314.70 that Mutual sought, correct?
15 A. Yes.
16 Q. Exhibit 330 is a fifth example of
17 a special supplement label change that
18 Mutual sought, this time for thickness
19 of the tablets, right, in August 2002?
20 A. Yes.
21 Q. Exhibit 331 is a sixth example of
22 a special supplement label change --
23 strike that.
24 Exhibit 331, in September 2002, is
25 a sixth example of a special supplement
00250
1 that Mutual sought this time regarding
2 raw material method testing, correct?

Objection (249:12 to 250:8):
-402

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 250:5 - 250:8

THE WITNESS: This is a --
6 such a supplement. I have lost track of
7 how many now we have looked at, so I
8 don't know if this is the sixth or not.

Witness_ Robert Dettery - Vol. 1.txt: 251:11 - 251:16

Q. And I did not ask you, regarding
12 this risk of SJS and TEN from NSAID 2003
13 publication, is it correct that in 2003
14 Mutual never provided that publication
15 regarding NSAIDs, and specifically
16 sulindac and SJS and TEN, to the FDA?

Objection:
-402
-403 (no state law duty relevant to plaintiff's claims to submit literature to FDA)

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 1.txt: 251:21 - 251:22

THE WITNESS: To my
22 knowledge, we haven't submitted it.

Witness_ Robert Dettery - Vol. 1.txt: 252:1 - 252:5

Is it correct to
2 state that, to your knowledge, Mutual
3 has never submitted a 2003 publication
4 regarding NSAIDs, SJS, TEN, and sulindac
5 to the FDA?

Witness_ Robert Dettery - Vol. 1.txt: Page 252, Line 8

THE WITNESS: That's correct.

Witness_ Robert Dettery - Vol. 1.txt: 253:18 - 253:23

Q. You have already reviewed the
19 brand insert for 2004 today, and you
20 know that none of the information from
21 this 2003 publication was in the brand
22 insert or Mutual's insert a year later
23 in 2004, correct?

Witness_ Robert Dettery - Vol. 1.txt: Page 254, Line 1

THE WITNESS: Yes.

Witness_ Robert Dettery - Vol. 1.txt: 254:5 - 254:8

Q. Yes, it's correct that none of
6 that information from the 2003
7 publication was in the 2004 Mutual
8 label, correct?

Witness_ Robert Dettery - Vol. 1.txt: Page 254, Line 16

A. That's correct.

Bartlett v Mutual

Witness_ Robert Dettery - Vol. 2.txt: 261:1 - 261:22

VOLUME II,
IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW HAMPSHIRE
3
4
KAREN L. BARTLETT and
5 GREGORY S. BARTLETT,
Plaintiffs,
6 Case No.: 08-cv-358-JL
Judge Joseph N. Laplante
7 V
8
MUTUAL PHARMACEUTICAL
9 COMPANY, INC. and UNITED
RESEARCH LABORATORIES, INC,
10 Defendants.
11
12
13 SuperDeposition of ROBERT
14 DETTERY, taken at the law offices of
15 Segal, McCambridge, Singer & Mahoney,
16 Ltd., United Plaza, 30 South 17th
17 Street, Suite 1700, Philadelphia,
18 Pennsylvania, on Tuesday, September 1,
19 2009, at 11:32 a.m., before Jennifer L.
20 Bermudez, a Registered Professional
21 Reporter, and Notary Public, pursuant to
22 notice.

Witness_ Robert Dettery - Vol. 2.txt: 273:13 - 273:19

Q. Mr. Dettery, the benefit/risk
14 profile of a drug can change and often
15 does change over time, correct?
16 A. I don't know.
17 Q. Why do you not know?
18 A. Well, I'm not an expert in the
19 benefit/risk ratio of a product.

Objection:
-402
-602
-702
-Vague, ambiguous
-Calls for expert opinion
-Non-disclosed expert under 26(a)(2)

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 2.txt: 274:24 - 275:1

Do you agree, Mr. Dettery, that
25 the benefit/risk ratio of a product can
00275
1 change over the life of the product?

Objection (274:24 to 275:10):
-402
-602
-702
-Vague, ambiguous
-Calls for expert opinion
-Non-disclosed expert under 26(a)(2)

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 2.txt: 275:7 - 275:10

THE WITNESS: Well, to answer
8 your question, since FDA acknowledges
9 it, then I would have to say that that
10 must be the case.

Witness_ Robert Dettery - Vol. 2.txt: 276:2 - 276:6

Q. Do you agree that a new medical
3 report or study can identify a new use
4 for a drug which is beneficial, and when
5 that happens, the benefits of a drug can
6 improve or increase?

Bartlett v Mutual

Witness_ Robert Dettery - Vol. 2.txt: 276:13 - 277:5

THE WITNESS: Well, if a
14 new -- I am aware that with new evidence
15 of safety and effectiveness, that a
16 product may get a new indication, but I
17 can't say if that relates to a better
18 benefit for the product.
19 BY MR. JENSEN:
20 Q. Can you state on the other side of
21 the coin, that an example of such as a
22 medical report or study can provide
23 information about how a labeled event,
24 like SJS and TEN, might occur or it can
25 provide information about serious
00277
1 complications of a labeled event, like
2 blindness or coma, and that would be
3 providing additional risk information
4 that has been learned of through medical
5 reports or studies?

Objection (276:2 to 276:18):
-402
-602
-702
-Vague, ambiguous
-Calls for expert opinion
-Non-disclosed expert under 26(a)(2)

Ruling: Overruled.

Objection (276:20 to 277:18):
-402
-602
-702
-Vague, ambiguous
-Calls for expert opinion
-Non-disclosed expert under 26(a)(2)

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 2.txt: 277:12 - 278:1

THE WITNESS: Again, I would
13 have to give you the same answer.
14 It's -- I don't necessarily conclude
15 that reports -- new -- new reports of
16 adverse events may relate to a change in
17 the risk profile of a product.
18 BY MR. JENSEN:
19 Q. Do you recall we had a discussion
20 about the relationship between the
21 Mutual entities, related entities, first
22 acquiring NDAs and the first time
23 Mutual, through Prosar, started doing
24 medical literature surveillance?
25 Do you recall that discussion we
00278
1 had?

Objection (277:19 to 278:23):
-402
-403
-407

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 278:5 - 278:18

THE WITNESS: I remember a
6 general discussion about that.
7 BY MR. JENSEN:
8 Q. Okay. Let me ask you
9 specifically.
10 Other than the reason you cited,
11 which was the fact that Mutual entities
12 started marketing NDA, also known as
13 brand name drugs, in 2006 or 2007, which
14 led to Mutual, through Prosar, starting
15 to do medical literature surveillance
16 for its ANDA, also known as generic
17 drugs, can you cite any other reason why
18 that occurred?

Witness_ Robert Dettery - Vol. 2.txt: 278:22 - 279:11

THE WITNESS: I'm not aware

23 of any other reason.
24 BY MR. JENSEN:
25 Q. Okay. Numerous times when I asked
00279
1 questions of you last week about whether
2 or not Mutual should be or should have
3 been surveying the medical literature or
4 assessing the adequacy of its label as
5 it pertained to sulindac before Karen
6 was prescribed it at the end of 2004,
7 you said Mutual was relying on the FDA
8 to ensure the sulindac label fully and
9 accurately set forth the risks and
10 benefits of their drugs in conjunction
11 with the brand name label. Correct?

Objection (278:25 to 279:16):
-Improper impeachment
-402

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 279:16 - 279:22

THE WITNESS: That's correct.
17 BY MR. JENSEN:
18 Q. And today, at least three times in
19 response to questions, I asked you about
20 whether you knew things and you talked
21 about your reliance on what the FDA told
22 you, right?

Objection (279:18 to 279:25):
-Improper impeachment
-402
-Vague
-Ambiguous

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 279:25 - 280:5

THE WITNESS: Yes.
00280
1 BY MR. JENSEN:
2 Q. And you agree that a central
3 mission of the FDA is to ensure the
4 health and safety of the U.S. populous,
5 right?

Objection (280:2 to 280:21):
-402
-403
-Seeks improper opinion

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 2.txt: 280:9 - 280:18

THE WITNESS: Yes. My
10 understanding of the mission of FDA is
11 consumer protection.
12 BY MR. JENSEN:
13 Q. And that mission of consumer
14 protection of the FDA includes drug
15 labels that do not overstate the
16 benefits nor understate the risks
17 associated with drugs in package
18 inserts, also known as labels, right?

Witness_ Robert Dettery - Vol. 2.txt: Page 280, Line 21

THE WITNESS: Yes.

Witness_ Robert Dettery - Vol. 2.txt: 281:23 - 282:2

Q. But you agree that the FDA, to
24 assess medical literature, either needs
25 to go and survey literature themselves
00282
1 or they need to get it from some source
2 so they can assess it, right?

Objection (281:23 to 282:12):
-402
-403 (FDA not a defendant)
-602
-Improper opinion

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 282:7 - 282:21

THE WITNESS: Well, yes. My
8 understanding of FDA is that they are
9 relying on scientific information that
10 they either search themselves or receive
11 from the brand -- the NDA holder of the
12 brand product.
13 BY MR. JENSEN:
14 Q. Hence, part of the FDA's mission
15 for consumer protection, which was your
16 words, was when medical literature is
17 obtained, it needs to be assessed by
18 somebody to determine whether or not
19 that medical information requires or
20 warrants additional risk or additional
21 benefit information in a label, right?

Objection (282:14 to 284:1):
-402
-403
-602
-Seeks improper opinion

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 283:15 - 283:20

THE WITNESS: Yes. I think
16 when FDA receives that information, they
17 assess it for the need to address if any
18 labeling changes are required.
19 BY MR. JENSEN:
20 Q. Or warranted, right?

Witness_ Robert Dettery - Vol. 2.txt: 283:25 - 284:1

THE WITNESS: Well, warranted
00284
1 or necessary, I consider it the same.

Witness_ Robert Dettery - Vol. 2.txt: 284:19 - 285:1

Q. Before Karen Bartlett ingested
20 sulindac in 2004, Mutual relied on the
21 FDA to have enough medical experts and
22 enough resources to monitor and assess
23 the relevant medical literature and the
24 accuracy and adequacy of drug labels in
25 conjunction with the brand name
00285
1 manufacturers, right?

Objection (284:19 to 285:24):
-402
-403
-602
-Improper opinion
-Argumentative

Ruling: Sustained as to lines 285:6 through 285:24. Otherwise overruled.

Witness_ Robert Dettery - Vol. 2.txt: 285:4 - 285:10

THE WITNESS: Yes.
5 BY MR. JENSEN:
6 Q. Now, a generic maker, like Mutual,
7 does not know whether or not the brand
8 name maker is accurately or adequately
9 reporting the medical literature to the
10 FDA, right?

Witness_ Robert Dettery - Vol. 2.txt: 285:13 - 285:20

THE WITNESS: No, we would
14 not know that.
15 BY MR. JENSEN:
16 Q. A generic maker, like Mutual, does
17 not know whether or not the brand name

18 manufacturer is assessing the medical
19 literature and/or reporting it to the
20 FDA, right?

Witness_ Robert Dettery - Vol. 2.txt: 285:23 - 285:24

THE WITNESS: No, I would not
24 agree with that.

Witness_ Robert Dettery - Vol. 2.txt: 286:16 - 286:22

A generic maker, A, doesn't know
17 whether the brand name manufacturer is
18 submitting medical literature to the
19 FDA, and a generic maker also does not
20 know, B, whether the brand name
21 manufacturer is assessing the medical
22 literature, correct?

Objection (286:16 to 288:20):
-402
-403
-602
-Seeks improper opinion
-Argumentative

Ruling: Sustained as to lines 286:16 through 288:8. Otherwise overruled.

Witness_ Robert Dettery - Vol. 2.txt: 286:25 - 287:15

THE WITNESS: Well, A, it's
00287
1 the brand company's obligation to report
2 it, so I have to assume that they are.
3 Although, I don't have direct knowledge
4 that they do.
5 And, B, I have to assume that
6 if FDA is receiving it, they are
7 assessing it.
8 BY MR. JENSEN:
9 Q. And as you pointed out, all a
10 generic company has is the assumptions
11 that the medical literature surveillance
12 and the assumption that medical
13 literature assessment is going on, and
14 it has no knowledge one way or the
15 other, correct?

Witness_ Robert Dettery - Vol. 2.txt: 287:19 - 288:5

THE WITNESS: I have the
20 assumption that the brand companies are
21 fulfilling their obligation to report
22 medical literature, and I'm assuming
23 that FDA is fulfilling its mission in
24 assessing such literature.
25 BY MR. JENSEN:
00288
1 Q. In short, a generic maker has to
2 assume that those things are happening
3 to conclude that the drug label is a
4 full and accurate statement of the risks
5 and benefits, right?

Witness_ Robert Dettery - Vol. 2.txt: 288:8 - 288:15

THE WITNESS: Yes.
9 BY MR. JENSEN:
10 Q. Now, if it were the case that the
11 FDA has more than enough qualified
12 experts and more than enough resources

13 to achieve its mission before 2004, then
14 Mutual's reliance would have been well-
15 placed, right?

Witness_ Robert Dettery - Vol. 2.txt: 288:18 - 289:4

THE WITNESS: I have to
19 assume that FDA has such resources
20 available to them.
21 BY MR. JENSEN:
22 Q. How many times before 2004 did
23 Mutual ever investigate or assess
24 whether or not that was true, whether or
25 not the FDA had sufficient resources to
00289
1 keep up with whether or not drug labels
2 provide full and accurate assessments of
3 the risks and benefits of the thousands
4 of market drugs?

Objection (288:22 to 291:10):
-402
-403
-602
-Seeks improper opinion
-Argumentative

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 2.txt: 289:8 - 289:20

THE WITNESS: That is
9 something that the company just -- we
10 don't question FDA on whether or not
11 they are capable of doing their jobs.
12 BY MR. JENSEN:
13 Q. Okay. How many times before 2004,
14 a different question, did a Mutual
15 investigator assess whether or not the
16 FDA had sufficient resources and
17 expertise to keep up with, let alone
18 assess, the new medical literature
19 pertaining to thousands of marketed
20 drugs?

Witness_ Robert Dettery - Vol. 2.txt: 289:23 - 290:7

THE WITNESS: Same question,
24 it is not a company's -- or same answer,
25 it is not a company's duty to -- or
00290
1 obligation to question FDA if they have
2 the resources or expertise to properly
3 do their job.
4 BY MR. JENSEN:
5 Q. Don't you agree that Mutual's
6 reliance on the adequacy of the FDA's
7 resources, then, was blind reliance?

Witness_ Robert Dettery - Vol. 2.txt: 290:11 - 290:14

THE WITNESS: My experience
12 with FDA and working in the industry is
13 such that FDA is quite capable of doing
14 their job and fulfilling their mission.

Witness_ Robert Dettery - Vol. 2.txt: 290:17 - 291:1

Q. You told me what you think you
18 know about the FDA. You told me that
19 Mutual never has investigated or

20 assessed whether or not the FDA has had
21 sufficient resources.
22 So in terms of the assuming that
23 the FDA had sufficient resources to
24 fulfill its mission regarding drug
25 labels, Mutual's reliance was a blind
00291
1 reliance, was it not?

Witness_ Robert Dettery - Vol. 2.txt: 291:8 - 291:10

THE WITNESS: Well, again,
9 we -- I have no reason to believe that
10 FDA is incapable of doing their job.

Witness_ Robert Dettery - Vol. 2.txt: 291:14 - 292:8

First, I'm going to show you who
15 cites these studies. In 2009, the U.S.
16 Supreme Court ruled in a case called
17 Wyeth vs. Levine, and I'm going to flip
18 back here and show you what they cited
19 about the FDA.
20 They first said, in 1955, the year
21 the agency approved a particular drug,
22 an FDA advisory committee issued a
23 report finding conclusively that the
24 budget and staff of the Food and Drug
25 Administration are inadequate to permit
00292
1 the discharge of its existing
2 responsibilities for the protection of
3 the American public.
4 Do you see that, sir?
5 A. Yes.
6 Q. Were you aware of that -- I know
7 it's a long time ago, but you might have
8 been aware.

Objection (291:14 to 297:9):
-402 (FDA not a defendant)
-403
-602
-Improper publishing
-Improper opinion
-Argumentative
-801
-802

Ruling: Sustained. The plaintiff may present evidence of the FDA's alleged lack of resources or inability to monitor drug safety, but this is not a proper means of doing so.

Witness_ Robert Dettery - Vol. 2.txt: 292:15 - 293:3

But were you aware of that finding
16 a long time ago in 1955?
17 A. No, I was not aware of that.
18 Q. Thank you, sir.
19 Well, let's step up then to a more
20 recent finding.
21 The U.S. Supreme Court also found
22 it appropriate to tell in this opinion
23 about a report called FDA Science Board
24 Report of the Subcommittee on Science
25 and Technology, "FDA Science and Mission
00293
1 at Risk," and it was a 2007 report.
2 Are you aware of anything to do --
3 or any of the findings of that report?

Witness_ Robert Dettery - Vol. 2.txt: 293:19 - 294:12

A. I'm not aware of the content of
20 that report.
21 Q. And here is one thing that the

22 U.S. Supreme Court told us that this
23 2007 report said, they quoted them as
24 saying, "The agency suffers from serious
25 scientific deficiency and is not
00294
1 positioned to meet current or emerging
2 regulatory responsibilities."
3 Did I read that right?
4 A. That's what it says.
5 Q. And we are going to get to that
6 very report in a second. Here it is.
7 It is the "FDA Science and Mission at
8 Risk," published in November 2000.
9 But before we do, sir, I'm going
10 to show you some testimony from one of
11 the main authors of that report, and his
12 name is Dr. Cassell.

Witness_ Robert Dettery - Vol. 2.txt: 295:4 - 297:1

Q. I'm going to represent to you,
5 Mr. Dettery, that Dr. Cassell was one of
6 the authors of this 2007 report, "FDA
7 Science and Mission at Risk" and show
8 you some of his testimony to the U.S.
9 Congress.
10 And then I'm going to ask you
11 whether or not the findings or his
12 testimony have any influence upon your
13 long-term reliance on the sufficiency of
14 the FDA's resources.
15 Do you understand what I'm going
16 to ask you to do, sir?
17 A. I believe so, yes.
18 Q. Dr. Cassell -- first of all, let's
19 show you who he is.
20 Dr. Cassell says, he is the VP of
21 scientific affairs and a distinguished
22 research scholar of infectious diseases
23 at a drug company called Eli Lilly.
24 Ever heard of that drug company,
25 sir?
00296
1 A. Yes.
2 Q. He says -- he testifies to the
3 U.S. Congress, he is a professor and
4 chairman, and I am going to abbreviate,
5 the Department of Microbiology at the
6 Alabama Medical School, he is a member
7 of the Institute of Medicine, the
8 National Academy of Sciences, and is
9 currently serving a second term on the
10 Board of the Institute of Medicine.
11 Do you see that, sir?
12 A. Yes.
13 Q. He swears that he appears before
14 the U.S. Congress as a member of the FDA
15 Science Board Advisory Committee to the
16 FDA Commissioner, and he served as the
17 chair of the subcommittee on this.
18 He says, I served on the science
19 and technology, the Science Board, which

20 authored the report "FDA Science and
21 Mission at Risk."
22 Do you see that?
23 A. Yes.
24 Q. So we understand, if his testimony
25 was honest, that he's a drug industry
00297
1 person. Fair?

Witness_ Robert Dettery - Vol. 2.txt: 297:5 - 297:6

Q. He's from Eli Lilly company. He's
6 a drug industry person, correct?

Witness_ Robert Dettery - Vol. 2.txt: 297:8 - 297:9

THE WITNESS: Well, he works
9 for Eli Lilly, yes.

Witness_ Robert Dettery - Vol. 2.txt: 297:23 - 299:16

He says the record -- he swears,
24 the record of the proceedings of that
25 meeting will show that due to the
00298
1 seriousness of the deficiencies found
2 and the urgency of the situation, the
3 Science Board was adamant that the
4 report be broadly disseminated among the
5 public and policy makers, including the
6 posting of it in the Federal Register.
7 Do you see that?
8 A. Yes.
9 Q. And he describes this report, "FDA
10 Science and Mission at Risk," as only
11 the second time in over a century, long
12 before we were born, that the agency,
13 the FDA, has been reviewed by an
14 external committee as a whole entity.
15 Do you see that?
16 A. Yes.
17 Q. And he says, "The expertise and
18 level of accomplishments of the members
19 are almost unprecedented in a single
20 committee."
21 That's what this gentleman swears
22 to, fair?
23 A. That's what it says.
24 Q. And he says -- he tells us who
25 this committee comprises.
00299
1 He swears it included a Nobel
2 laureate in pharmacology, 14 members of
3 the National Academy of Sciences, a
4 renowned economist, a leader in
5 healthcare policy, a former CEO of a
6 large pharmaceutical company, a former
7 Assistant Secretary of Health and Human
8 Services, who also headed global
9 regulatory affairs with a large company
10 for over 24 years -- excuse me -- 20
11 years, a former chief counsel for the

Objection (297:23 to 299:25):
-402 (FDA not a defendant)
-403
-602
-Improper publishing
-Improper opinion
-Argumentative
-801
-802

Ruling: Sustained.

12 FDA, and the first Under Secretary For
13 Food Safety at the U.S. Department of
14 Agriculture.
15 That's who he says was on his
16 team, if you will. Fair?

Witness_ Robert Dettery - Vol. 2.txt: Page 299, Line 25

A. That's what it says, yes.

Witness_ Robert Dettery - Vol. 2.txt: 300:18 - 301:5

Because the question I asked you,
19 sir, is, if you know of a better, bigger
20 analysis of whether or not the FDA can
21 meet its proclaimed mission of consumer
22 protection and public health, whether or
23 not it has sufficient resources.
24 You might know that two years
25 before this there was a bigger or better
00301
1 analysis done. So you either know that
2 or you don't, sir.
3 Do you know of a better or bigger
4 analysis than what this one appears to
5 be?

Objection (300:18 to 310:22):
-402 (FDA not a defendant)
-403
-602
-Improper publishing
-Improper opinion
-Argumentative
-801
-802

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 301:11 - 301:13

THE WITNESS: I am not aware
12 of any other assessment, other than this
13 one that you are presenting here now.

Witness_ Robert Dettery - Vol. 2.txt: 301:16 - 302:7

Dr. Cassell went on to testify, he
17 says, "It became readily apparent that
18 the FDA suffers from serious scientific
19 deficiencies and is not positioned to
20 meet current or emerging regulatory
21 responsibilities."
22 Did I read that right?
23 A. That's what it says, yes.
24 Q. He goes on to swear to the
25 Congress, "Since every regulatory
00302
1 decision must be based upon the best
2 available scientific evidence in order
3 to protect the public's health, we
4 conclude that American lives are at risk
5 and there's an urgent need to address
6 deficiencies."
7 Is that what it says?

Witness_ Robert Dettery - Vol. 2.txt: 302:13 - 302:20

THE WITNESS: That's what it
14 says.
15 BY MR. JENSEN:
16 Q. Okay. He goes on to testify to
17 the Congress, "What we found is quite
18 simply demands of FDA have soared over

19 the past two decades," and he emphasizes
20 resources have not. Right?

Witness_ Robert Dettery - Vol. 2.txt: 303:1 - 303:17

THE WITNESS: Again, that's
2 what the report says -- or this
3 document.
4 BY MR. JENSEN:
5 Q. And he says his subcommittee found
6 that -- and he has a number of bullet
7 points. Let me go to the third one
8 here.
9 He says, "FDA cannot adequately
10 monitor development of new medical
11 products and adequately evaluate the
12 safety of existing products because it
13 is unable to keep up with scientific
14 advances," and then there's a
15 parenthetical.
16 That's what he swore to that his
17 subcommittee found, correct?

Witness_ Robert Dettery - Vol. 2.txt: Page 304, Line 1

That's what it says,

Witness_ Robert Dettery - Vol. 2.txt: 304:6 - 304:10

Q. The last bullet point reads, "The
7 FDA cannot fulfill its mission because
8 its scientific workforce does not have
9 sufficient capacity or capability.
10 Correct?

Witness_ Robert Dettery - Vol. 2.txt: 304:15 - 304:23

THE WITNESS: That's what it
16 says.
17 BY MR. JENSEN:
18 Q. His next bullet point says, "The
19 FDA cannot fulfill its mission because
20 its information technology
21 infrastructure is sorely inadequate. It
22 is problematic at best and at worst it
23 is dangerous." Correct?

Witness_ Robert Dettery - Vol. 2.txt: 305:5 - 305:6

THE WITNESS: That's what it
6 says.

Witness_ Robert Dettery - Vol. 2.txt: 305:13 - 305:21

He testified at Page 6 here,
14 "Specifically we found that the FDA's
15 shortfalls have resulted in a plethora
16 of inadequacies that threaten our
17 society, including, but not limited to,"
18 and then his second bullet point under
19 that is, "a dearth of scientists who
20 understand emerging new technologies."

21 Is that what he swore to?

Witness_ Robert Dettery - Vol. 2.txt: 305:25 - 306:7

THE WITNESS: That's what the
00306
1 document says.
2 BY MR. JENSEN:
3 Q. His last bullet point on that page
4 reads, "An information technology
5 infrastructure that was identified as a
6 source of risk in every center and
7 program reviewed by the subcommittee."

Witness_ Robert Dettery - Vol. 2.txt: 306:11 - 306:23

THE WITNESS: That's what's
12 written.
13 BY MR. JENSEN:
14 Q. Dr. Cassell, this Eli Lilly drug
15 company senior vice president, also
16 swore to the U.S. Congress that,
17 "Without immediate action, injuries and
18 death from an overwhelmed regulatory
19 system are certain and the cost to our
20 society will be far greater than any
21 dollar figure upon which we can arrive
22 at."
23 That's what he said, right?

Witness_ Robert Dettery - Vol. 2.txt: 307:6 - 307:13

THE WITNESS: Again, that's
7 what it says in the document.
8 BY MR. JENSEN:
9 Q. Do you agree that the portions of
10 the testimony I just read to you of
11 Dr. Cassell, from the Eli Lilly drug
12 company, that he gave last year in 2008,
13 are alarming?

Witness_ Robert Dettery - Vol. 2.txt: 307:20 - 308:12

THE WITNESS: You are asking
21 for my opinion, and I don't have an
22 opinion formed at this moment.
23 BY MR. JENSEN:
24 Q. Okay. Well, just as a human
25 being, sir, when Dr. Cassell, this, I
00308
1 represent, distinguished drug company
2 representative, is on a subcommittee
3 that does an obviously intensive,
4 detailed evaluation of whether the FDA
5 can live up to its mission of consumer
6 protection and protection of the public
7 health, and he testifies, this drug
8 company vice president, that without
9 immediate action, injuries and deaths
10 from an overwhelmed regulatory system
11 are certain, don't you find that
12 alarming?

Witness_ Robert Dettery - Vol. 2.txt: 308:21 - 308:25

THE WITNESS: I don't -- I
22 can't answer your question because,
23 again, I don't have an opinion.
24 BY MR. JENSEN:
25 Q. That's not alarming to you?

Witness_ Robert Dettery - Vol. 2.txt: 309:3 - 309:13

THE WITNESS: No.
4 BY MR. JENSEN:
5 Q. Okay. Is it concerning to you
6 that this FDA that you have been putting
7 so much reliance on over the years has
8 been found very recently to be in such a
9 bad situation that unless immediate
10 action is taken, injuries and deaths
11 from an overwhelmed regulatory system
12 are certain?
13 Is that concerning to you, sir?

Witness_ Robert Dettery - Vol. 2.txt: 309:20 - 310:13

THE WITNESS: I have no
21 opinion whether that is concerning or
22 not.
23 BY MR. JENSEN:
24 Q. I'm not asking for an opinion.
25 I'm just asking for -- as a person
00310
1 who works in regulatory affairs, who
2 works on and has relied on the FDA, as
3 you testified many times last week and
4 today, you rely on the FDA to have
5 enough resources, you rely on them to
6 assess medical literature.
7 And now I'm showing you evidence
8 that this review has found that the FDA
9 has insufficient resources and that
10 deaths and injuries are certain from an
11 overwhelmed regulatory system.
12 I'm just asking, as a person,
13 doesn't that concern you?

Witness_ Robert Dettery - Vol. 2.txt: 310:21 - 310:22

THE WITNESS: I don't have
22 enough evidence to form an opinion.

Witness_ Robert Dettery - Vol. 2.txt: 312:8 - 312:17

Q. Isn't it true, to your knowledge,
9 Mutual has done nothing to look into
10 whether the conclusions of this November
11 2007 report, "FDA Science and Mission at
12 Risk," were correct, and has done
13 nothing to determine whether or not its
14 chairman from the drug industry's
15 conclusion was correct that because of
16 an overwhelmed regulatory system

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17 injuries and deaths are certain?

Objection (312:8 to 314:15):
-402 (FDA not a defendant)
-403
-602
-Improper publishing
-Improper opinion
-Argumentative
-801
-802

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 312:21 - 312:22

Q. To your knowledge, Mutual has done
22 nothing in that regard; isn't that true?

Witness_ Robert Dettery - Vol. 2.txt: 313:9 - 313:16

THE WITNESS: Again, I can't
10 speak on behalf of others in the company
11 if they did anything in regards to this
12 report.
13 BY MR. JENSEN:
14 Q. To your knowledge, no one at
15 Mutual did anything in regard to these
16 reports and findings, correct?

Witness_ Robert Dettery - Vol. 2.txt: 313:21 - 314:5

THE WITNESS: Like I said
22 before, I have no knowledge of what
23 others in the company may have done.
24 BY MR. JENSEN:
25 Q. And you don't know that they did
00314
1 anything regarding this, right?
2 You don't have any affirmative
3 knowledge that anyone at Mutual ever did
4 anything to look into the reports,
5 right?

Witness_ Robert Dettery - Vol. 2.txt: 314:12 - 314:15

THE WITNESS: Again, I don't
13 know what others in the company may have
14 done, if anything, possible, as follow-
15 up to this report.

Witness_ Robert Dettery - Vol. 2.txt: 316:1 - 316:25

And let's start with the
2 first page. Exhibit 419 is what we have
3 just been speaking about, the "FDA
4 Science and Mission at Risk" report,
5 published under two years ago, authored
6 in part by its chair, that we just read
7 his testimony, Dr. Cassell.
8 Starting with the first
9 page. Have you ever seen the first page
10 of this report before, sir?
11 A. Are you calling the title page the
12 first page?
13 Q. Yes, sir.
14 A. No.
15 Q. Okay. I'm going to, again, go
16 through some of its findings with you
17 and ask you whether or not these
18 findings affect the propriety or whether
19 it was a good idea to be relying on the
20 FDA to have sufficient resources to
21 carry out its mission of protecting the

Objection (316:1 to 321:8):
-402 (FDA not a defendant)
-403
-602
-Improper publishing
-Improper opinion
-Argumentative
-801
-802

Ruling: Sustained.

22 public and consumer protection.
23 Do you understand what I'm asking
24 you to do, sir?
25 A. Yes.

Witness_ Robert Dettery - Vol. 2.txt: 317:4 - 317:20

In relation to the things I read
5 to you out of Dr. Cassell's testimony,
6 did some or all of those things,
7 Mr. Dettery, cause you to be concerned
8 about whether it was a good idea for
9 Mutual to be relying on the presumption
10 that the FDA had sufficient resources,
11 without ever looking into it, to protect
12 the consumers and to ensure public
13 health?
14 MR. COSGROVE: Objection.
15 Form. Foundation. Complex.
16 Confusing. Misleading.
17 THE WITNESS: I believe you
18 already did ask me that. And as I
19 replied, at this point, I have no
20 opinion.

Witness_ Robert Dettery - Vol. 2.txt: 317:24 - 319:2

Let's start on Page 5. And tell
25 me when you are there, sir.
00318
1 A. I'm there.
2 Q. At the top, you will see this
3 actual report stated, "FDA's failure to
4 retain and motivate its workforce put
5 FDA's mission at risk.
6 "Inadequately trained scientists
7 are generally risk adverse and tend to
8 give no decision, a slow decision or
9 even worse the wrong decision on
10 regulatory approval or disapproval."
11 Is that what it says so far?
12 A. That's what it says.
13 Q. It says, "During our encounters
14 with staff and center leadership, we
15 were struck by the mere unanimity that
16 the shortage of science staff due to
17 lack of resources to hire and the
18 inability to recruit and retain needed
19 expertise are serious, long-standing
20 challenges."
21 Is that what they reported?
22 A. That's what it says.
23 Q. It says, it goes on, "The
24 subcommittee was extremely disturbed at
25 the state of the FDA, IT --" you
00319
1 understand that stands for information
2 technology -- "infrastructure." Right?

Witness_ Robert Dettery - Vol. 2.txt: 319:6 - 319:12

THE WITNESS: That's what it

says.
BY MR. JENSEN:
Q. And it goes on to say, "The FDA
lacks the information technology
infrastructure necessary to meet its
mandate." Correct?

Witness_ Robert Dettery - Vol. 2.txt: 319:15 - 319:25

THE WITNESS: That's what it
says.
BY MR. JENSEN:
Q. It says, "The IT situation at FDA
is problematic at best and at worse it
is dangerous. Systems fail" --
And it goes on to say, "Systems
fail frequently and even e-mail systems
are unstable most recently during an E.
coli food contamination investigation."
Is that what it says in part?

Witness_ Robert Dettery - Vol. 2.txt: 320:4 - 320:14

THE WITNESS: That's what it
says in part, yes.
BY MR. JENSEN:
Q. Okay. And it goes on, on the
bottom of that page, to report that,
"Critical data reside in large
warehouses sequestered in piles and
piles of paper documents, there is no
backup of these records, which include
valuable clinical trial data."
Is that what it says?

Witness_ Robert Dettery - Vol. 2.txt: 320:18 - 321:1

THE WITNESS: That's what it
says.
BY MR. JENSEN:
Q. Let's start with this: If any of
these things are true that I just read
to you, that's not a good thing for the
FDA's attempt to meet its mission to
safeguard the public, is it, or are
00321
they?

Witness_ Robert Dettery - Vol. 2.txt: Page 321, Line 8

THE WITNESS: I don't know.

Witness_ Robert Dettery - Vol. 2.txt: 322:3 - 322:10

If it's true that the FDA lacks
sufficient resources to hire and has an
inability to recruit and retain needed
expertise, do you agree that that is not
a good thing in terms of the FDA's
attempts to meet its mission to ensure
the health and safety of the American
populous?

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Witness_ Robert Dettery - Vol. 2.txt: 322:19 - 322:22

THE WITNESS: I don't have
20 enough information to -- to make a
21 determination whether your statement is
22 correct or not.

Objection (322:3 to 322:22):
-402 (FDA not a defendant)
-403
-602
-Improper publishing
-Improper opinion
-Argumentative
-801
-802

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 323:8 - 323:19

if it's true, as
9 was reported by the "FDA Science and
10 Mission at Risk" report, that as they
11 reported that there is insufficient
12 resources to hire and an inability to
13 recruit and retain needed expertise --
14 that's not what I'm saying, that's what
15 the report is saying -- if that is true,
16 do you agree, Mr. Dettery, that that is
17 not a good thing for the FDA's ability
18 to achieve its mission to protect the
19 American public?

Objection (323:8 to 325:6):
-402 (FDA not a defendant)
-403
-602
-Improper publishing
-Improper opinion
-Argumentative
-801
-802

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 324:1 - 324:19

THE WITNESS: I don't have
2 enough information in order to agree or
3 disagree with it.
4 BY MR. JENSEN:
5 Q. Okay. Let's go to the IT
6 infrastructure that you referenced.
7 If it's true that the FDA lacks
8 the IT infrastructure necessary to meet
9 its mandate, and if it's true, as
10 Dr. Cassell testified, that the FDA
11 cannot fulfill its mission because its
12 information technology infrastructure is
13 thoroughly inadequate, which is
14 problematic at best and at worst
15 dangerous, in his testimony, do you
16 agree that those are not good things for
17 the FDA's ability to meets its mission
18 to ensure the safety of the American
19 populous?

Witness_ Robert Dettery - Vol. 2.txt: 325:4 - 325:6

THE WITNESS: I don't have
5 sufficient information in order to agree
6 or disagree with the report.

Witness_ Robert Dettery - Vol. 2.txt: 326:4 - 327:4

Q. The U.S. Supreme Court this year
5 not only quoted a portion of the report
6 that we have been looking at, "FDA
7 Science and Mission at Risk," it also
8 reported some other recent findings.
9 A 2007 report of the National
10 Academies of the Institutes of Medicine,
11 entitled "The Future of Drug Safety,
12 Promoting and Protecting the Health of

13 the Public."
14 Do you see that, sir?
15 A. I see where you have just
16 highlighted, yes.
17 Q. Thank you, sir.
18 And the U.S. Supreme Court quoted
19 the National Academies of Science to
20 say, in 2007, just two years ago, "The
21 FDA lacks the resources needed to
22 accomplish this large and complex
23 mission.
24 "There is widespread agreement
25 that the resources for post marketing
00327
1 drug safety" -- let me stop there.
2 That's what we have been talking
3 about, post-marketing drug safety, today
4 and the last time, in large part, right?

Objection (326:4 to 328:1):
-402 (FDA not a defendant)
-403
-602
-Improper publishing
-Improper opinion
-Argumentative
-801
-802

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 327:9 - 327:11

THE WITNESS: Well, there are
10 various aspects of post-marketing drug
11 safety.

Witness_ Robert Dettery - Vol. 2.txt: 327:17 - 327:20

Q. In relation to the regulatory
18 affairs aspect of proper labeling, that,
19 of course, relates to post-marketing
20 drug safety, correct?

Witness_ Robert Dettery - Vol. 2.txt: 327:23 - 328:9

THE WITNESS: The labeling
24 could relate to post-marketing drug
25 safety when it's a branded product,
00328
1 that's correct.
2 BY MR. JENSEN:
3 Q. The reason Mutual unilaterally,
4 prior to FDA approval, found it
5 appropriate to change the Qualaquin
6 label to add additional enhanced risk
7 information regarding the risk of
8 thrombocytopenia was to enhance post-
9 marketing drug safety, correct?

Objection (328:3 to 328:9):
-402
-403
-407
-Does not designate the answer

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: Page 329, Line 3

yes.

Objection:
-402, -403, -407,
-Vague, -Did not designate the question

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 329:10 - 329:23

Q. So a U.S. Supreme Court reported
11 that, in 2007, the National Academies of
12 Sciences said, "The FDA lacks the
13 resources needed to accomplish its large
14 and complex mission.
15 "There is widespread agreement
16 that resources for post marketing drug
17 safety work are especially inadequate

18 and that resource limitations have
19 hobbled the agency's ability to improve
20 and expand this essential component of
21 its mission."
22 Is that what it was reporting
23 here?

Objection (329:10 to 330:22):
-402 (FDA not a defendant)
-403
-602
-Improper publishing
-Improper opinion
-Argumentative
-801
-802

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 330:5 - 330:7

THE WITNESS: Well, you
6 correctly read the part that you
7 highlighted.

Witness_ Robert Dettery - Vol. 2.txt: 330:10 - 330:15

Q. Do you agree with the quote that
11 is in here, to the extent and to the
12 effect where it says that post-marketing
13 drug safety work is an essential
14 component of its mission, referring to
15 the FDA's mission?

Witness_ Robert Dettery - Vol. 2.txt: 330:19 - 330:22

THE WITNESS: I couldn't
20 agree or disagree with that. I don't
21 know what the basis of that comment was
22 about.

Witness_ Robert Dettery - Vol. 2.txt: 331:23 - 332:7

Do you agree that a part of -- a
24 critical part of FDA's mission of
25 protection of the American populous
00332
1 is -- better if I pronounce the word
2 right.
3 New question: Do you agree that a
4 critical part and essential part of the
5 FDA's mission of protecting the health
6 of the U.S. populous is post-marketing
7 drug safety?

Objection (331:23 to 332:22):
-402
-403
-602
-Calls for opinion

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 332:17 - 333:5

THE WITNESS: I don't know if
18 I would be able to answer that. I don't
19 know everything that FDA does to protect
20 the consumer health. So I don't know
21 what -- how the post-marketing safety
22 relates to the entire picture of FDA.
23 BY MR. JENSEN:
24 Q. What did Mutual do to look into
25 whether this finding was justified or
00333
1 not justified, that the lack of
2 resources have hobbled the FDA's ability
3 to improve and expand this essential
4 component of its mission which they
5 refer to as post-marketing drug safety?

Objection (332:24 to 335:8):
-402 (FDA not a defendant)
-403
-602
-Improper Publishing

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 333:10 - 333:16

-Improper opinion
-Argumentative
-801
-802

And I don't know what Mutual
11 did.
12 BY MR. JENSEN:
13 Q. To your knowledge, Mutual did
14 nothing to look into that, correct?
15 A. Again, I don't know what anyone
16 else in the company may have done.

Witness_ Robert Dettery - Vol. 2.txt: 334:1 - 334:16

In
2 footnote 11, the U.S. Supreme Court also
3 cited a report by the Government
4 Accounting Office, drug safety
5 improvement needed in FDA's post-
6 marketing decision making, and that was
7 published in 2006.
8 Do you see that, sir?
9 A. I see where you just highlighted,
10 yes.
11 Q. And the quote that the U.S.
12 Supreme Court provided from that is,
13 "FDA lacks a clear and effective process
14 for making decisions about and providing
15 management oversight of post market
16 safety issues." Correct?

Witness_ Robert Dettery - Vol. 2.txt: 334:20 - 334:25

THE WITNESS: Again, the part
21 that you highlighted is what he said.
22 BY MR. JENSEN:
23 Q. And the part I highlighted is a
24 complete highlight of the U.S. Supreme
25 Court's quote as it appears here, right?

Witness_ Robert Dettery - Vol. 2.txt: Page 335, Line 8

THE WITNESS: Yes.

Witness_ Robert Dettery - Vol. 2.txt: 336:4 - 336:8

Objection (336:4 to 336:14):
-402 (FDA not a defendant)
-403
-602
-Improper publishing
-Improper opinion
-Argumentative
-801
-802

Ruling: Sustained.

Does this finding
5 of the FDA, in the same study, concern
6 you, "FDA does not have the capacity to
7 ensure the safety of food for the
8 nation"? Yes or no?

Witness_ Robert Dettery - Vol. 2.txt: 336:12 - 336:14

THE WITNESS: I can't give
13 you a yes or no answer. I don't know.
14 I don't have an opinion on it.

Witness_ Robert Dettery - Vol. 2.txt: 338:17 - 338:25

In our discussion here, before we
18 got to these documents, you pointed out
19 that you were not only relying on the
20 FDA to do its job and have sufficient
21 resources to do its job, but you were

22 relying on the name brand manufacturer
23 to do its job and go and get that
24 medical literature and assess it,
25 correct?

Objection (338:17 to 340:11):
-402 (FDA not a defendant)
-403
-602
-Improper publishing
-Improper opinion
-Argumentative
-801
-802

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 339:6 - 339:24

THE WITNESS: I believe what
7 I said is that I have no reason to
8 believe FDA is incapable of doing their
9 job, and that it is the branded
10 company's obligation, rather than the
11 generic company's, to provide post-
12 marketing safety information to FDA.
13 BY MR. JENSEN:
14 Q. Let's just go to the one part of
15 your answer there.
16 If Dr. Cassell from the drug
17 industry, and all these people that he
18 coauthored this report with, got these
19 findings right, his ultimate conclusion
20 that injuries and death are certain from
21 an overwhelmed regulatory system, do you
22 now have reason to be concerned about
23 whether Mutual's reliance on the FDA's
24 adequate resources was well-placed?

Witness_ Robert Dettery - Vol. 2.txt: 340:7 - 340:11

THE WITNESS: Again, my
8 answer is the same as before. I have --
9 I don't have enough information to be --
10 to form an opinion about whether that is
11 concerning or not.

Witness_ Robert Dettery - Vol. 2.txt: 344:17 - 344:20

Is it correct
18 to state, sir, that for all matters of
19 regulatory affairs at Mutual, from 1991
20 through 2004, the buck stopped with you?

Objection (344:17 to 345:4):
-Vague
-Ambiguous
-Argumentative

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 2.txt: 344:25 - 345:4

THE WITNESS: As I testified
00345
1 previously, since 1993 I have been vice
2 president of the Regulatory Affairs
3 Department, and that is the top position
4 within that department.

Witness_ Robert Dettery - Vol. 2.txt: 345:15 - 345:18

There's never been a
16 regulatory affairs person above you from
17 1993 through 2004, correct?
18 A. That's correct.

Witness_ Robert Dettery - Vol. 2.txt: 346:9 - 346:12

Q. Hence, to the best of your
10 recollection, for those 13 years the

11 regulatory affairs decisions, the buck
12 always has stopped with you. Fair?

Objection (346:9 to 346:21):
-Vague
-Ambiguous
-Argumentative

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 2.txt: 346:17 - 346:21

THE WITNESS: Well, I don't
18 know what you mean by "the buck stops
19 here." But, as I said, I was in charge
20 of that department for that period of
21 time.

Witness_ Robert Dettery - Vol. 2.txt: 347:4 - 347:12

Q. Flip to Exhibit 11. Tell me when
5 you are there, sir.
6 A. Exhibit 11?
7 Q. Yes, sir.
8 And that is a 1987 publication
9 entitled, "A fatal case of sulindac
10 induced Lyell syndrome," which they
11 define as toxic epidermal necrolysis.
12 Correct?

Objection (347:4 to 347:19):
-402
-403
-602
-Improper publishing
-Seeks opinion testimony
-801
-802

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 347:18 - 347:19

that is what it appears
19 the title is, correct.

Witness_ Robert Dettery - Vol. 2.txt: 348:14 - 349:7

Q. And just so we have a date range,
15 so we know what the date is, does 303
16 allow you to confirm, sir, that the
17 approval date for sulindac was April 17,
18 1991?
19 A. Yes.
20 Q. And what date -- that's the
21 approval date.
22 Now, tell us what the initial
23 application date was by Mutual for
24 sulindac.
25 A. May 20th, 1987.
00349
1 Q. Thank you, sir.
2 Understanding you were not there,
3 but understanding you can learn things
4 after you arrive, is it correct to state
5 that, to the best of your knowledge,
6 this 1987 report was never provided by
7 Mutual to the FDA?

Objection (349:1 to 350:8):
-402
-403 (state law claims don't rely upon giving literature to FDA)

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 349:13 - 349:25

THE WITNESS: I don't know if
14 this has ever been produced or not. It
15 says generic company. It's not likely
16 that we have, but I don't know for sure.
17 BY MR. JENSEN:
18 Q. And, also, you have no
19 knowledge -- we are only going to do
20 this for about three or four articles.
21 The question is, you have no

22 knowledge and Mutual would have no
23 knowledge that the brand name holder
24 ever provided this publication to the
25 FDA, correct?

Witness_ Robert Dettery - Vol. 2.txt: 350:4 - 350:15

THE WITNESS: I don't know if
5 anybody at Mutual is aware that this has
6 been submitted to FDA by the brand
7 company or not.
8 BY MR. JENSEN:
9 Q. Is it correct to state that
10 generic companies typically do not
11 receive the filings of brand name
12 companies when they submit medical
13 literature as post-marketing -- in post-
14 marketing periodic reports?
15 A. That is correct.

Objection (350:9 to 350:15):
-402
-403

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 351:9 - 351:13

Q. Is the next publication that I'm
10 showing you, Mr. Dettery, appear to you
11 to be a 1988 publication entitled
12 "Sulindac Induced Toxic Epidermal
13 Necrolysis"?

Objection (351:9 to 358:6):
-402
-403
-602
-801
-802
-702
-Improper publishing
-Seeks opinion testimony

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 351:17 - 352:4

THE WITNESS: It's a
18 document, I don't know of what type,
19 that has a subtitle that reads as you
20 read.
21 BY MR. JENSEN:
22 Q. Okay. And if it's true to what it
23 appears to be, which is a medical
24 publication and clinical pharmacy where
25 they say sulindac induced toxic
00352
1 epidermal necrolysis, we know from those
2 four or five words that somebody is
3 concluding that somebody got TEN from
4 sulindac, right?

Witness_ Robert Dettery - Vol. 2.txt: 352:11 - 352:17

THE WITNESS: I don't know.
12 BY MR. JENSEN:
13 Q. Okay. And this was the year --
14 1988 was while, as we just established,
15 Mutual's application was pending before
16 it was approved to market sulindac,
17 correct?

Witness_ Robert Dettery - Vol. 2.txt: 352:21 - 353:17

THE WITNESS: Well, it has
22 the date October 1988 on there.
23 BY MR. JENSEN:
24 Q. Which is while the application was
25 pending, correct?

00353
A. I forget what the -- the
submission date was May 20th?
Q. It was 1987 --
A. '87.
Q. -- was the submission and '91 was
the approval.
So this was while the initial
application was pending, correct?
A. So October 1988 does fall between
those two dates, right.
Q. Thank you.
And a statement in this
publication is that clinicians should be
aware of the risk of TEN with sulindac
and should monitor patients
appropriately for dermatological
reactions, correct?

Witness_ Robert Dettery - Vol. 2.txt: 353:23 - 354:8

THE WITNESS: Well, the
portion of the entire document that you
highlighted reads that way.
00354
BY MR. JENSEN:
Q. Okay. And, to your knowledge,
isn't it true that Mutual never did
anything to bring to the attention of
the FDA this conclusion that clinicians,
meaning doctors, should be aware of the
risk that this deadly skin disease is
associated with sulindac?

Witness_ Robert Dettery - Vol. 2.txt: 354:14 - 355:3

THE WITNESS: I don't know if
that was ever done or not.
BY MR. JENSEN:
Q. And you also don't know whether or
not the name brand ever provided this to
the FDA, correct?
A. Well, as I previously said, we
don't get copies of what the brand
company submits to FDA, so I would have
to rely that they did.
Q. Talking about assumptions and
reliances, you don't know the name brand
00355
manufacturer provided this to the FDA,
correct?
A. As I --

Witness_ Robert Dettery - Vol. 2.txt: 355:6 - 355:8

THE WITNESS: As I answered,
I don't know what the name brand company
submits to FDA,

Witness_ Robert Dettery - Vol. 2.txt: 355:13 - 355:17

Q. We discussed for a bit, in your

14 prior day we spoke, this publication
15 which came out -- the jury won't be able
16 to see it, but do you see it says
17 February 2003 at the bottom there?

Witness_ Robert Dettery - Vol. 2.txt: 356:4 - 356:12

THE WITNESS: It says,
5 Revision Accepted February 2003. I
6 don't know when it was published.
7 BY MR. JENSEN:
8 Q. Thank you, sir.
9 And it's entitled -- and I am
10 going to abbreviate -- "The risk of SJS
11 and TEN associated with NSAIDs a
12 multinational perspective." Correct?

Witness_ Robert Dettery - Vol. 2.txt: 356:16 - 356:20

THE WITNESS: That is the
17 header on this document, yes.
18 BY MR. JENSEN:
19 Q. And as we discussed, sulindac is
20 an NSAID, right?

Witness_ Robert Dettery - Vol. 2.txt: 356:24 - 357:20

THE WITNESS: As I recall,
25 yes.
00357
1 BY MR. JENSEN:
2 Q. And sulindac is referenced in this
3 document, as we discussed, on page 2771,
4 right where I just highlighted.
5 If you can look at the screen
6 right between the tables there.
7 A. I see ketoprofen and other NSAIDs.
8 Q. Yes, sir. And right here where my
9 thumb is, do you see sulindac?
10 A. No. There is something in the
11 way. Now, move it up a little.
12 Q. Yes, sir.
13 A. I see you highlighted the word
14 "sulindac."
15 Q. Thank you.
16 And you see from here other NSAIDs
17 has a footnote, and the footnote
18 represents a number of NSAIDs including
19 sulindac, as we just referenced,
20 correct?

Witness_ Robert Dettery - Vol. 2.txt: 357:25 - 358:6

THE WITNESS: I see a
00358
1 footnote for Other NSAIDs, and I see
2 approximately 15 or so products included
3 under that footnote under Other NSAIDs.
4 BY MR. JENSEN:
5 Q. Including sulindac, correct?
6 A. Including sulindac.

Witness_ Robert Dettery - Vol. 2.txt: 361:2 - 361:18

Mr. Dettery, assume for me the
3 following is true, and then I'm going to
4 ask you a question: Assume for me that
5 this 2003 study concluded that
6 ketoprofen, one NSAID, had no
7 relationship with people getting SJS or
8 TEN from that particular NSAID.
9 And, secondly, this study also
10 included that other NSAIDs did have what
11 is called a statistically significant
12 association with getting SJS or TEN.
13 I'm asking you to assume that's true.
14 Do you, sir, as a regulatory
15 affairs official, agree that that would
16 have been important information for
17 doctors prescribing NSAIDs to know in
18 2003 or 2004?

Objection (361:2 to 363:24):
-402
-403
-602
-801
-802
-702
-Improper publishing
-Seeks opinion testimony
-Plaintiff's counsel changed witness' answer

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 362:2 - 362:5

THE WITNESS: Well, I
3 believe, as I testified last week, I'm
4 not a physician, I don't know what
5 information is important to a physician,

Witness_ Robert Dettery - Vol. 2.txt: 362:14 - 362:23

Is it correct, Mr. Dettery,
15 that, to your knowledge, no one at
16 Mutual ever assessed, analyzed,
17 investigated or questioned whether or
18 not this was important information for
19 doctors to have, specifically that one
20 NSAID had no relationship to these
21 highly deadly diseases and that other
22 NSAIDs did have strong relationships to
23 these highly deadly skin conditions?

Witness_ Robert Dettery - Vol. 2.txt: 363:7 - 363:9

I don't know if this
8 document has been assessed by anyone at
9 Mutual.

Witness_ Robert Dettery - Vol. 2.txt: 363:14 - 363:19

to the best of your
15 knowledge, no one at Mutual ever
16 assessed, questioned or investigated
17 whether or not this was important
18 information for prescribing doctors to
19 have, correct?

Witness_ Robert Dettery - Vol. 2.txt: 363:24 - 364:3

THE WITNESS: I don't know.
25 BY MR. JENSEN:
00364
1 Q. Are adverse drug reactions a big
2 problem for the health of the American

3 public, Mr. Dettery?

Objection (364:1 to 364:25):
-402
-403
-602
-702
-Seeks improper opinion

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 364:7 - 364:17

THE WITNESS: I really have
8 no opinion on that. I don't know.
9 BY MR. JENSEN:
10 Q. Okay. Well, you have frequently
11 given testimony that you rely on the FDA
12 to ensure the health and safety of the
13 American populous.
14 Tell us, you are a regulatory
15 affairs official for some 20 years, are
16 adverse drug reactions a significant
17 cause of death amongst Americans?

Witness_ Robert Dettery - Vol. 2.txt: 364:24 - 365:19

THE WITNESS: I don't know if
25 they are or not.
00365
1 BY MR. JENSEN:
2 Q. 422, for the record. Here is a
3 copy for you, Mr. Dettery. Exhibit 422,
4 sir, was published in JAMA.
5 And you understand that to be the
6 Journal of the American Medical
7 Association, correct?
8 A. Yes.
9 Q. And it was published, as you can
10 see, in 2002, correct?
11 A. It was, yes, 2002.
12 Q. And the lead sentence in this
13 Journal of the American Medical
14 Association, 2002 publication, two years
15 before Karen Bartlett is prescribed
16 sulindac, says, "Adverse drug reactions
17 are believed to be a leading cause of
18 death in the United States."
19 Is that what this reports?

Objection (365:2 to 368:24):
-402
-403
-602
-702
-801
-802
-Seeks opinion testimony
-Plaintiff's counsel changed witness' answers

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 366:2 - 366:10

The sentence says
3 that "Adverse drug reactions are
4 believed to be a leading cause of death
5 in the United States."
6 BY MR. JENSEN:
7 Q. Do you have any idea what the
8 estimations are as to how many deaths in
9 the United States are caused yearly by
10 adverse drug reactions?

Witness_ Robert Dettery - Vol. 2.txt: 366:14 - 366:19

THE WITNESS: No.
15 BY MR. JENSEN:
16 Q. Exhibit 423 is another publication
17 in the Journal of the American Medical
18 Association. This time in 2005.
19 Correct?

Witness_ Robert Dettery - Vol. 2.txt: 366:22 - 367:6

THE WITNESS: It says 2005 on
23 it.
24 BY MR. JENSEN:
25 Q. All right. And it's first
00367
1 sentence tells us that the Journal of
2 the American Medical Association, it
3 says, in 2005, "Adverse drug and device
4 reactions account for as many as one
5 hundred thousand deaths annually."
6 Correct?

Witness_ Robert Dettery - Vol. 2.txt: 367:10 - 367:22

THE WITNESS: The highlighted
11 first sentence reads as you have stated.
12 BY MR. JENSEN:
13 Q. Let's go back to the prior one in
14 2002.
15 And it says its objective of this
16 study would "determine the frequency and
17 timing of new adverse drug reactions
18 described in black box warnings or
19 necessitating withdrawal of the drug
20 from the market."
21 That's the claimed objective,
22 right?

Witness_ Robert Dettery - Vol. 2.txt: 368:1 - 368:13

THE WITNESS: That's what it
2 says.
3 BY MR. JENSEN:
4 Q. And, in part, its results are,
5 that 45 drugs, 8.2 percent, acquired one
6 or more black box warnings and 16, 2.9
7 percent, were withdrawn from the market,
8 it goes on, in Kaplan & Meyer analyses,
9 "The estimated probability of acquiring
10 a new black box warning or being
11 withdrawn from the market over 25 years
12 was 20 percent."
13 Do you see that, sir?

Witness_ Robert Dettery - Vol. 2.txt: 368:23 - 368:24

what you stated is what the highlighted
24 sentence reads.

Witness_ Robert Dettery - Vol. 2.txt: 369:4 - 369:8

Q. And a black box warning is what,
5 please, Mr. Dettery?
6 A. It's a section of the labeling
7 with warnings about that particular
8 product.

Witness_ Robert Dettery - Vol. 2.txt: 369:13 - 370:17

When a black box

14 appears on the label it's on the very
15 top, is that correct, right under the
16 drug's listing?
17 A. I believe it is typically located
18 there, but I believe I have also seen it
19 in other areas of the labeling.
20 Q. Is a black box, to your
21 estimation, in 20 years of being a
22 regulatory affairs officer, done to make
23 a warning prominent for the reader?
24 A. My understanding is that FDA
25 requires black box warnings for the sake
00370
1 of prominence.
2 Q. What's underreporting,
3 Mr. Dettery?
4 A. In what regard?
5 Q. Adverse event regard.
6 A. I can give you my interpretation
7 of what it means.
8 Q. Okay.
9 A. That there are more adverse events
10 that occur than there are reports from
11 the patient or the doctor to the company
12 or to FDA.
13 Q. Fair to say you have seen
14 publications that estimate the amount of
15 reporting at one percent to ten percent,
16 meaning that 99 percent to 90 percent of
17 reactions are not reported?

Objection (369:13 to 370:1):
-402
-403 (only FDA can institute Black Box Warning)
-Seeks opinion testimony

Ruling: Overruled.

Objection (370:2 to 371:7):
-402 (reporting rates have no bearing on plaintiff's state law claims)
-403
-Foundation
-602
-702
-Seeks opinion testimony

Ruling: Sustained as to lines 370:13 through 371:7. Otherwise overruled.

Witness_ Robert Dettery - Vol. 2.txt: 370:23 - 371:7

THE WITNESS: I don't know
24 what the percentages are.
25 BY MR. JENSEN:
00371
1 Q. Have you ever seen any
2 publications that attempt to estimate
3 how much underreporting occurs, whether
4 it is 90 percent or 99 percent, or any
5 other number?
6 A. I don't recall if I have seen any
7 such publications or not.

Witness_ Robert Dettery - Vol. 2.txt: 371:20 - 372:7

Looking at the adverse reports,
21 you have rash and you have TEN,
22 different ends of the spectrum, I submit
23 to you.
24 Do you have any reason to believe
25 that reports of rash versus TEN might be
00372
1 any higher or lower than one, because
2 TEN is, obviously, a much more serious
3 event and, therefore, one might
4 conclude, hypothetically, that it is
5 reported at a higher percent rate than a
6 rash?
7 Do you know one way or the other?

Objection (371:20 to 372:18):
-402
-403
-602
-702
-Foundation
-Seeks opinion testimony

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 372:11 - 372:18

THE WITNESS: Are you
12 speaking specifically of sulindac or
13 anything?
14 BY MR. JENSEN:
15 Q. Let's start with anything.
16 A. I really don't know.
17 Q. Then I will speak of sulindac.
18 A. I really don't know that either.

Witness_ Robert Dettery - Vol. 2.txt: 378:12 - 378:19

Q. And does that appear to be a 2004
13 publication in drug safety, sir?
14 A. That's what it appears to be.
15 Q. And does it appear to be titled
16 "Evaluation of the extent of
17 underreporting of serious adverse drug
18 reactions the case of toxic epidermal
19 necrolysis"?

Objection (378:12 to 383:22):
-402
-403
-602
-702
-801
-802
-Improper publishing

Ruling: Sustained as to lines 378:12 through 383:9. Otherwise overruled.

Witness_ Robert Dettery - Vol. 2.txt: 379:5 - 379:13

the
6 header states what you said.
7 BY MR. JENSEN:
8 Q. And just as a reference for CIHI,
9 it's a reference to Canadian Institute
10 for Health Information.
11 Do you see that here in this
12 paragraph, under the Patient Group
13 Studied, sir?

Witness_ Robert Dettery - Vol. 2.txt: 379:16 - 380:6

THE WITNESS: Yes.
17 BY MR. JENSEN:
18 Q. And the results of the study
19 were -- first of all, it talks about
20 objective. The objective was to examine
21 the extent of underreporting of TEN in
22 the country of Canada, correct?
23 A. That's what it says.
24 Q. Its results were 25 TEN cases, six
25 fatal, were reported to this
00380
1 abbreviation, which stands for Canadian
2 adverse drug reaction monitoring
3 program, from January '95 to December
4 2000.
5 So for about five years,
6 correct?

Witness_ Robert Dettery - Vol. 2.txt: 380:9 - 380:24

THE WITNESS: That's what it
10 says.
11 BY MR. JENSEN:
12 Q. It goes on to report that, during
13 this period, 14, about 63 percent, burn
14 treatment sites reported an admission of

15 250 TEN cases.
16 It goes on to say, "Using the burn
17 facility as a denominator, ten percent,
18 25 of 250, of TEN cases were reported to
19 that entity."
20 Using the other entity, the
21 Canadian Institute for Health
22 Information data as a denominator, only
23 four percent, 25 of 674 cases of TEN
24 were reported. Correct?

Witness_ Robert Dettery - Vol. 2.txt: 381:5 - 381:19

THE WITNESS: You have
6 accurately stated the highlighted
7 portion of this document that you gave
8 me to read.
9 BY MR. JENSEN:
10 Q. And the conclusion of this
11 document is, "There is a serious
12 underreporting of TEN. Lack of
13 reporting of life-threatening adverse
14 drug reactions can compromise population
15 safety.
16 "There is a need to increase
17 awareness of adverse drug reporting
18 programs," as they reported in 2004.
19 Correct?

Witness_ Robert Dettery - Vol. 2.txt: 382:11 - 382:13

A. You have accurately portrayed the
12 highlighted section of this document
13 that you gave me to read.

Witness_ Robert Dettery - Vol. 2.txt: 383:10 - 383:22

"QUESTION: Do you agree,
11 Mr. Dettery, that when one, therefore,
12 has one, two, five reports of TEN in
13 relation to any given drug, that one is
14 not justified in concluding those are
15 the only one, two or five cases that
16 have actually occurred in relation to
17 that drug?")
18 MR. COSGROVE: The same
19 objection.
20 THE WITNESS: I have no basis
21 to agree with that -- with that
22 conclusion

Witness_ Robert Dettery - Vol. 2.txt: 384:16 - 385:4

The following entities, to your
17 knowledge, all who knew Karen Bartlett
18 had TEN and all of whom knew she took
19 sulindac didn't report it; A, Harvard,
20 B, Northeast Rehab, C, Spaulding
21 Rehabilitation Institute, D, when she
22 went back Caritas Family Hospital.
23 Representing to you those were
24 four places Karen Bartlett was after

Objection (384:16 to 385:17):
-402
-403
-602
-Speculation foundation
-Contains commentary of counsel
-Facts not in evidence

Ruling: Overruled.

25 they knew she took sulindac and after
00385
1 they knew she had TEN, you know because
2 of the absence of a report from them
3 that none of those fine institutions
4 made such a report, right?

Witness_ Robert Dettery - Vol. 2.txt: 385:15 - 385:17

THE WITNESS: All I can say
16 is that until this lawsuit, we were
17 unaware of this event, we had no report.

Witness_ Robert Dettery - Vol. 2.txt: 386:9 - 386:13

Q. Exhibit 425, sir. This appears to
10 be published in the Journal of American
11 Dermatology in 1989.
12 You see the bottom of the
13 abstract, correct?

Objection (386:9 to 390:20):
-402
-403
-602
-801
-802
-Improper publishing
-Plaintiff's counsel altered witness' answer

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 386:17 - 386:19

THE WITNESS: That's what it
18 appears to say at the bottom of the
19 abstract, correct.

Witness_ Robert Dettery - Vol. 2.txt: 386:23 - 387:3

And it goes on to state,
24 "Although rare, its germatic nature,
25 extremely high morbidity" -- and you
00387
1 understand morbidity to mean other
2 things that might occur in relation to
3 it, right?

Witness_ Robert Dettery - Vol. 2.txt: 387:8 - 387:17

THE WITNESS: What do you
9 mean by other things in relation to it?
10 BY MR. JENSEN:
11 Q. Well, I'll give you some examples
12 for TEN. Sepsis, renal failure, liver
13 failure, all your skin falling off,
14 those are things that are morbidities
15 which happen to be associated with TEN.
16 But you understand that that's
17 what the word "morbidity" means, right?

Witness_ Robert Dettery - Vol. 2.txt: 387:21 - 387:25

THE WITNESS: My
22 understanding of the term "morbidity" is
23 that it's illness or some type of a
24 physiological problem.
25 BY MR. JENSEN:

Witness_ Robert Dettery - Vol. 2.txt: 388:2 - 388:8

So it goes on and says, referring
3 to TEN, "And a relatively high

4 mortality."
5 And you understand that to be the
6 relatively high rate at which people
7 succumb or die from the disease,
8 correct?

Witness_ Robert Dettery - Vol. 2.txt: 388:19 - 388:23

THE WITNESS: Well, if you
20 are asking me what the definition of
21 mortality is, I would agree that the
22 definition of mortality is the -- is a
23 death rate.

Witness_ Robert Dettery - Vol. 2.txt: 389:4 - 389:11

And this report says, "Because of
5 extremely high morbidity and a
6 relatively high mortality," referring to
7 TEN, "it perhaps" -- I'll insert the
8 word "is" -- "the most important drug
9 related cutaneous eruption with respect
10 to assessing risk and benefit of a
11 drug." Correct?

Witness_ Robert Dettery - Vol. 2.txt: 389:17 - 389:21

THE WITNESS: The -- what you
18 stated I believe is an accurate
19 portrayal of the highlighted section of
20 this entire document that you gave me to
21 look at.

Witness_ Robert Dettery - Vol. 2.txt: 390:6 - 390:10

Q. And it lists drugs that it says --
7 the title of Table 3 is, Drugs
8 considered responsible for causing, I
9 will abbreviate, TEN, in present study
10 and some other studies. Fair?

Witness_ Robert Dettery - Vol. 2.txt: 390:13 - 390:20

THE WITNESS: It says that,
14 and plus French series and Washington
15 series, whatever that means.
16 BY MR. JENSEN:
17 Q. Thank you.
18 And amongst the drugs that it
19 listed as considered responsible for
20 causing TEN is sulindac, correct?

Witness_ Robert Dettery - Vol. 2.txt: Page 391, Line 1

I see sulindac

Witness_ Robert Dettery - Vol. 2.txt: 393:21 - 393:24

Q. Do you see that this study lists
22 that there are two cases of TEN where
23 sulindac was identified as the drug
24 considered responsible for causing it?

Objection (393:21 to 394:9):
-402
-403
-602

Bartlett v Mutual

Witness_ Robert Dettery - Vol. 2.txt: 394:7 - 394:9

it appears
8 to show to me that there were two cases
9 reported for sulindac.

-801
-802
-Improper publishing
-Plaintiff's counsel altered witness' answer

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 395:11 - 395:16

This 1989 publication, to your
12 knowledge, this was while Mutual's
13 initial ANDA, also known as generic
14 application, was pending, to the best of
15 your knowledge, was not provided to the
16 FDA by Mutual, correct?

Objection (395:11 to 396:11):
-402
-403 (state law claims don't depend on providing data to FDA)
-602

Ruling: Sustained.

Witness_ Robert Dettery - Vol. 2.txt: 395:22 - 396:7

THE WITNESS: I don't know if
23 it was provided or not.
24 BY MR. JENSEN:
25 Q. And, to your knowledge, this 1989
00396
1 study was not provided by the FDA --
2 strike that.
3 To your knowledge, this 1989
4 publication was not provided to the FDA
5 by the branded drug company?
6 You might assume that, but you
7 don't know that, right?

Witness_ Robert Dettery - Vol. 2.txt: 396:10 - 396:11

THE WITNESS: I don't know if
11 it was or not.

Witness_ Robert Dettery - Vol. 2.txt: 396:24 - 397:17

Q. First, let's start out, the
25 branded name for sulindac is Clinoril.
00397
1 Correct?
2 A. Yes.
3 Q. When you speak of Clinoril, you
4 are speaking of the same chemical entity
5 as sulindac, correct?
6 A. The same active moiety, correct.
7 Q. Correct.
8 Mutual's sulindac drug has been
9 shown to be bioequivalent to Clinoril's
10 sulindac, correct?
11 A. Correct.
12 Q. What that means is, to the best of
13 everyone's knowledge, there will be the
14 same risk and benefit profile associated
15 with Mutual's sulindac as you would
16 presume is associated with the brand
17 name Clinoril. Fair?

Witness_ Robert Dettery - Vol. 2.txt: Page 397, Line 18

correct.

Witness_ Robert Dettery - Vol. 2.txt: 401:9 - 401:23

Q. And do you understand the label
10 starting on 2799 to be the label that
11 was being changed pursuant to the FDA's
12 direction?
13 A. I don't know if this was the label
14 that FDA was referring to or not.
15 Q. I'm asking you to presume it was
16 for purposes of my question.
17 Let's go ahead and flip to page
18 2805. Tell me when you are there.
19 A. I'm there.
20 Q. And we addressed this language,
21 and it says, "NSAIDs including
22 Clinoril," which we know is sulindac,
23 correct, under Skin Reactions?

Objection (401:9 to 405:10):
-402
-403
-407 (Rx date 12/04)
-Seeks opinion testimony

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 2.txt: 402:4 - 402:12

Q. So where it says, "NSAIDs
5 including Clinoril, which is sulindac,
6 can cause serious adverse events such as
7 exfoliative dermatitis, Stevens-Johnson
8 Syndrome, SJS, and toxic epidermal
9 necrolysis, TEN, which can be fatal,"
10 that's the language that you and Mutual
11 believe and agree is true and accurate,
12 correct?

Witness_ Robert Dettery - Vol. 2.txt: 402:18 - 403:13

THE WITNESS: This is a --
19 well, you are asking me to presume that
20 this is an accurate representation of
21 the actual insert. I don't know. All I
22 can say is what you said is what is
23 written here.
24 BY MR. JENSEN:
25 Q. And without showing you the label,
00403
1 I asked you last time we were with each
2 other whether the Mutual label that now
3 says that NSAIDs including sulindac can
4 cause SJS and TEN was true and accurate,
5 and you said, we believe our labels are
6 true and accurate, hence, yes.
7 Now I'm just showing you the very
8 language that you have already agreed
9 to.
10 Do you believe this language,
11 which I have just highlighted and read,
12 is true and accurate, and does Mutual as
13 well?

Witness_ Robert Dettery - Vol. 2.txt: 403:17 - 404:1

THE WITNESS: I stated that I
18 believed our labeling was true and
19 accurate, and I don't know if this is
20 the accurate portrayal of the true

21 label.
22 BY MR. JENSEN:
23 Q. You do know that Mutual's label,
24 just like this sentence, does say that
25 NSAIDs including sulindac can cause SJS
00404
1 and TEN, right?

Witness_ Robert Dettery - Vol. 2.txt: 404:6 - 405:5

THE WITNESS: I would need to
7 refer to our labeling again to answer
8 that.
9 BY MR. JENSEN:
10 Q. Well, let me read you my question
11 and your answer and see if you still
12 agree to it, Mr. Dettery.
13 I asked you, "Do you agree that
14 Mutual agrees that its label for
15 sulindac is accurate as of March 2006
16 where it states sulindac causes SJS and
17 TEN are accurate and true?"
18 And your answer was, "I would say
19 that our labeling is an accurate
20 representation of the referenced drug's
21 labeling as we can make it."
22 Then I asked, "Mutual has a label
23 for its sulindac product that says SJS
24 and TEN are caused by sulindac. Does
25 Mutual agree that label is true and
00405
1 accurate?"
2 And you answered, "As far as I
3 know, our labeling is as true and as
4 accurate as we can make it."
5 Do you stand by that testimony?

Witness_ Robert Dettery - Vol. 2.txt: 405:9 - 405:10

THE WITNESS: I agree with
10 what you just read to me.

Witness_ Robert Dettery - Vol. 2.txt: 408:21 - 408:24

does Exhibit 353 appear to
22 you to be sulindac's label by Mutual?
23 Look on Page 22 for the answer.
24 A. It appears to be.

Objection (408:21 to 410:3):
-402
-403
-407 (Rx date 12/04)
-Seeks opinion testimony

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 2.txt: 409:7 - 410:3

Tell me when you are
8 there.
9 A. There.
10 Q. And it reads, tell me if I have
11 read it correctly, "NSAIDs including
12 sulindac tablets can cause serious skin
13 adverse reactions such as exfoliative
14 dermatitis, Stevens-Johnson Syndrome,
15 SJS, and toxic epidermal necrolysis,
16 TEN, which can be fatal."
17 Did I read that correctly?

18 A. Well, you used the term "skin
19 adverse reactions" and it really says
20 "events." But other than that, you
21 correctly read it.
22 Q. Thank you.
23 And this, what I just read with
24 your correction, is in the Warnings
25 section of a label, correct?
00410
1 A. Yes.
2 Q. Okay. Let's go back to the
3 sentence that's highlighted on Page 9.

Witness_ Robert Dettery - Vol. 2.txt: 410:23 - 411:1

Q. Okay. And this is your labeling
24 and, as far as you know, it is true and
25 accurate that sulindac causes SJS and
00411
1 TEN, correct?

Objection (410:23 to 411:8):
-402
-403
-407 (Rx date 12:04)
-Seeks opinion testimony

Ruling: Overruled.

Witness_ Robert Dettery - Vol. 2.txt: 411:7 - 411:8

THE WITNESS: It's as
8 accurate as we can make it.
